

STUDY

Requested by the JURI committee



The potential impact of the unitary Supplementary Protection Certificate on access to health technologies



Policy Department for Citizens' Rights and Constitutional Affairs
Directorate-General for Internal Policies
PE 753.104 - September 2023

The potential impact of the unitary Supplementary Protection Certificate on access to health technologies

Analysis of regulatory proposals

Abstract

In April 2023, the European Commission adopted regulatory proposals introducing a Unitary Supplementary Protection Certificate (SPC) and a centralised assessment procedure for SPCs for medicinal products. This study analyses the potential impacts of these proposals on access to medicines, the administrative burden to applicants and the cost to national health systems.

This document was prepared by Policy Department for Citizens' Rights and Constitutional Affairs at the request of the JURI Committee.

This document was requested by the European Parliament's Committee on Legal Affairs (JURI).

AUTHORS

Thyra DE JONGH, Technopolis B.V.

Bregtje KAMPHUIS, Technopolis B.V.

Sven BOSTYN, Faculty of law, University of Copenhagen

Alfred RADAUER, Institute Business Administration and Management, IMC Krems University of Applied Sciences

ADMINISTRATOR RESPONSIBLE

Giorgio MUSSA

Mariusz MACIEJEWSKI

EDITORIAL ASSISTANT

Ewelina MIAZGA

LINGUISTIC VERSIONS

Original: EN

ABOUT THE EDITOR

Policy departments provide in-house and external expertise to support EP committees and other parliamentary bodies in shaping legislation and exercising democratic scrutiny over EU internal policies.

To contact the Policy Department or to subscribe for updates, please write to:

Policy Department for Citizens' Rights and Constitutional Affairs

European Parliament

B-1047 Brussels

Email: Poldep-Citizens@ep.europa.eu

Manuscript completed in September 2023

© European Union, 2023

This document is available on the internet at:

<http://www.europarl.europa.eu/supporting-analyses>

DISCLAIMER AND COPYRIGHT

The opinions expressed in this document are the sole responsibility of the authors and do not necessarily represent the official position of the European Parliament. Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the European Parliament is given prior notice and sent a copy.

© Cover image used under licence from Adobe Stock.com

CONTENTS

LIST OF BOXES	6
LIST OF FIGURES	6
LIST OF TABLES	6
ABBREVIATIONS	7
DEFINITIONS	9
EXECUTIVE SUMMARY	11
1. GENERAL INFORMATION	18
1.1. Background to this study	18
1.2. About this study	18
1.3. Methodology and limitations	19
2. THE PHARMACEUTICAL SYSTEM IN THE EU	21
2.1. Pharmaceutical research and innovation	21
2.2. The role of intellectual property	22
2.2.1. Patents	23
2.2.2. Additional forms of market protection	28
2.3. Access to medicinal products	30
3. THE SPC SYSTEM: PAST, PRESENT AND FUTURE	33
3.1. The Supplementary Protection Certificate	33
3.1.1. Features of the existing SPC system	33
3.1.2. National differences in the SPC system	36
3.1.3. Trends in SPC applications in the European Union	37
3.1.4. Evaluation of the SPC system and rationale for change	38
4. PROPOSAL FOR A NEW SPC SYSTEM IN THE EU	39
4.1. Reasoning and options	39
4.2. Preferred options	40
4.3. The unitary SPC	41
4.3.1. Characteristics of the unitary SPC	41
4.3.2. Application procedure	42
4.3.3. Assessment procedure	42
4.3.4. Opposition and appeal	44
4.3.5. Decision on granting	44
4.3.6. Post-grant invalidation and appeal	47
4.4. Centralised national (non-unitary) SPC	48

4.4.1. Characteristics of the centralised SPC	48
4.4.2. Application procedure	48
4.4.3. Assessment procedure	49
4.4.4. Opposition and appeal	49
4.4.5. Decision on granting	49
4.4.6. Post-grant invalidation and appeal	50
4.5. Combined application	50
4.6. National SPCs	51
4.7. Examination authority	51
5. REVISIONS OF THE EU PHARMACEUTICAL LEGISLATIVE FRAMEWORK	53
5.1. The EU pharmaceutical legislative framework	53
5.2. Intersection between the EU pharmaceutical legislation and the SPC Regulation	54
5.2.1. Abolishment of the renewal and sunset clauses	55
5.2.2. Setting conditions on access to regulatory protections	57
5.2.3. Expanding the scope for the centralised procedure	61
5.2.4. Introduction of a transferable data exclusivity voucher for antimicrobials	62
6. POTENTIAL IMPACTS OF THE SPC REGULATIONS	64
6.1. Harmonisation and administrative simplification	64
6.1.1. Divergence of granting decisions	64
6.1.2. Rigour of the assessment and quality of the SPC certificate	65
6.1.3. Likelihood of litigation	67
6.1.4. Administrative streamlining	68
6.2. Cost implications	69
6.2.1. Costs for the central examination authority (EUIPO)	69
6.2.2. Application and maintenance fees	70
6.2.3. Translation costs	70
6.3. Access to medicines	71
6.3.1. Access to innovative medicines	71
6.3.2. Access to generic and biosimilar medicines	71
6.4. Transparency of information	73
6.5. Impact on healthcare budgets in Member States	74
7. POLICY RECOMMENDATIONS	76
7.1. Ensuring access to affordable medicines	76
7.1.1. Access to innovative medicines	76
7.1.2. Access to generic and biosimilar medicines	77
7.2. Support competitiveness, innovation and sustainability of industry	78

7.3. Additional considerations	79
7.3.1. Transfer of responsibilities from NPOs to the EUIPO	79
7.3.2. Standards of examination	80
7.3.3. Independence of Boards of Appeal	80
7.3.4. Cost impacts for applicants	80
REFERENCES	82

LIST OF BOXES

Box 1:	Difference between a traditional European patent and a European patent with unitary effect	27
Box 2:	Conditions for obtaining a unitary SPC	42
Box 3:	Objectives of the proposed EU general pharmaceutical legislation	54

LIST OF FIGURES

Figure 1:	Stages of medicinal product development	22
Figure 2:	Member States: European Patent Convention and AUPC	25
Figure 3:	Overview of procedures for obtaining a European patent	27
Figure 4:	System of intellectual property and regulatory protections on medicinal products in the EU	30
Figure 5:	Factors influencing access to medicines	32
Figure 6:	Current processes and procedures available in the SPC system	36
Figure 7:	Proposed procedure for obtaining a unitary SPC	46

LIST OF TABLES

Table 1:	Types of basic patents for medicinal products in Europe	24
Table 2:	Marketing authorisation pathways in the EU	31
Table 3:	Policy options considered for a unitary SPC	39
Table 4:	Overview of proposed procedures for obtaining an SPC	41
Table 5:	Options considered for modulating regulatory protection	57
Table 6:	Options considered for modulating orphan market exclusivity	59
Table 7:	Options considered for modulating the paediatric SPC extension	60
Table 8:	Product scope for the centralised procedure for marketing authorisation	62

ABBREVIATIONS

ADI	Application for declaration of invalidity
AUPC	Agreement on the Unified Patent Court
CMA	Conditional Marketing Authorisation
CJEU	Court of Justice of the European Union
EC	European Commission
EEC	European Economic Community
EFPIA	European Federation of Pharmaceutical Industry Associations
EMA	European Medicines Agency
EP	European Parliament
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
EUIPO	European Union Intellectual Property Office
EUR	Euro
IP	Intellectual Property
IT	Information Technology
HTA	Health Technology Assessment
MA	Marketing Authorisation
MS	Member State
NPO	National Patent Office
PIP	Paediatric Investigation Plan
R&D	Research and Development
SME	Small and Medium-sized Enterprises

SPC	Supplementary Protection Certificate
UK	United Kingdom
UP	Unitary Patent (also known as a European patent with unitary effect)
UPC	Unified Patent Court
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

DEFINITIONS

Competent authority	A medicines regulatory authority in the European Union.
Conditional Marketing Authorisation	The approval of a medicine that addresses unmet medical needs of patients on the basis of less comprehensive data than normally required. The available data must indicate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data in the future.
Generic medicine	A medicine that is developed to be the same as a medicine that has already been authorised. Its authorisation is based on efficacy and safety data from studies on the authorised medicine.
Innovative medicine	A medicine that contains an active substance or combination of active substances that has not been authorised before.
Medicinal product	A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.
Marketing Authorisation	The approval to market a medicine in one, several or all European Union Member States (depending on the authorisation procedure).
Marketing Authorisation Holder	The company or other legal entity that has the authorisation to market a medicine in one, several or all European Union Member States.
Reference medicine	A medicine already on the market that serves as a benchmark for the authorisation of a generic or biosimilar version of that medicine.
Supplementary Protection Certificate	A means of extending the term of patent exclusivity for a new medicine for a fixed period from the date of the first marketing authorisation in a European Union Member State.
Unitary Patent	An intellectual property right that provides patent protection in EU Member States that are party to the Agreement on a Unified Patent Court (AUPC) through a single application to the European Patent Office. It is formally known as a European patent with unitary effect.

- Unified Patent Court** An international court set up through the Agreement on a Unified Patent Court to deal with legal infringement and validity claims for European patents, with and without unitary effect.
- Unitary Supplementary Protection Certificate** An intellectual property right that extends the duration of a patent in a Member State by up to five years, granted at European level simultaneously for all countries that have ratified the AUPC.

EXECUTIVE SUMMARY

Background to the study

On 27 April 2023, the European Commission published a set of legislative proposals concerning the Supplementary Protection Certificate for medicinal products. Specifically, this concerns proposals for a:

- Regulation on the unitary supplementary protection certificate for medicinal products, and
- Recast of the Regulation on the SPC for medicinal products, introducing a new centralised procedure for the granting of national SPCs, as well as amendments to the current and remaining national procedure for the grant of national SPCs.

These proposals follow the introduction of the Unitary Patent and of the Unified Patent Court, stemming from the Agreement on a Unified Patent Court (AUPC), and intersect with various EU policy and legislative developments in the pharmaceutical space.

The JURI Committee for the European Parliament commissioned a team of experts, led by Technopolis Group, to conduct an analysis of the proposals and assess their potential impacts on access to medicines in the European Union. This document presents the results of that study. It aims to assist Members of the European Parliament in their assessment of the proposed Regulations.

The current SPC system

The Supplementary Protection Certificate (SPC) system was introduced by Regulation in the European Union in 1992. Its main purpose is to provide additional protection to patent holders for up to 5.5 years after the end of the basic patent, thereby allowing pharmaceutical companies more time to recover their research investment. This protection is crucial as the extensive testing and lengthy regulatory processes before medicinal products can be marketed eat into the patent's term. The SPC system aims to encourage pharmaceutical research and development, make the EU an attractive location for R&D investments, harmonize the internal market, and create a homogeneous SPC system.

To be eligible for an SPC, a product must have a basic patent in force, have a marketing authorisation in the EU, not have received a previous SPC, and be the first product with marketing authorisation in the EU. The duration of an SPC is calculated by subtracting five years from the time between the patent filing date and the marketing authorisation date, capped at a maximum of five years. An extension of this with six more months is possible for products for which an agreed paediatric investigation plan has been completed. The average duration of SPC protection is approximately 3.5 years. Whilst the conditions for granting are regulated at the EU level, SPC applications are currently submitted to national patent offices which assesses the application and grants or rejects it.

Despite the SPC Regulation's uniform criteria, national interpretations and practices vary across Member States. This includes differences in granting SPCs, their scope, expiry dates, and the availability of third-party observations. Transparency also differs among Member States, affecting the publication of SPC information. This situation leads to duplication of work, high costs, and inefficiencies. Furthermore, the territorial limitations of SPCs are seen as misaligned with the new unitary patent system. To address these issues, the Commission is proposing the introduction of a unitary SPC and amending the SPC Regulation.

Proposal for a new SPC system

The commission has explored five different policy options, ultimately settling on a combination of two of the options: 1) a centralised procedure resulting in the grant of national SPCs in some or all Member

States, and 2) a unitary procedure resulting in the grant of a single SPC in the Member States where the basic unitary patent is in place. An application combining these two options will also be possible. The current route of granting purely national SPCs will remain for nationally authorised products. Thus, with the proposed additions, there will effectively be four routes to obtaining an SPC in the EU.

The unitary SPC

The introduction of the unitary SPC is motivated by that of the unitary patent. It follows that a unitary SPC can be granted only for products protected by a unitary patent as the basic patent. This ensures that the patent claims are identical across all Member States. A second condition is that the marketing authorisation must have been granted through the EMA centralised procedure. All other requirements remain the same as under the current Regulation. The duration of a unitary SPC is calculated the same way as for a national SPC.

Applicants must apply for a unitary SPC with the EU Intellectual Property Office (EUIPO) within six months of receiving marketing authorisation or after unitary effect has been attributed to the basic patent. Applications can be filed in any official EU language. Application fees, as well as other possible fees (e.g., appeals or renewals), must be paid to the EUIPO.

Once an application has been filed, the EUIPO first assesses the formal admissibility of the application. Next, a central examination panel performs a substantive examination, focusing on eligibility conditions for a unitary SPC. During this time, third parties, including Member States, can provide written observations on the application's validity. The examination panel considers these observations but is not obliged to incorporate them into their decision. If the panel finds conditions are met, a positive examination opinion is issued; if not, a negative opinion is issued. The examination opinion is translated into all official EU languages.

Third parties can initiate an opposition procedure within two months after the publication of a positive examination opinion. Opposition applications are examined by an opposition panel and decided on within six months. The panel's decisions may be further appealed at the central level.

Once all processes for assessment, opposition, and appeal have been completed, the EUIPO decides whether to grant or reject the unitary SPC application. A unitary certificate confers the same rights and limitations as the basic patent in all Member States where the basic patent has unitary effect.

After granting, third parties still have the possibility to have an SPC invalidated, but only if it can be demonstrated that specific conditions have not been, or are no longer, met. An action for a declaration of invalidity must be filed before the EUIPO. Appeal against a decision to (not) declare an SPC invalid is possible at different levels, including the Boards of Appeal and the European General Court. Counterclaims for invalidity can also be filed before the Unified Patent Court (UPC).

The centralised SPC application

Alongside the unitary SPC, the Commission is proposing a second route based on a centralised assessment of applications, with a binding opinion issued by the examination authority. Centralised SPCs can be applied for using a European patent without unitary effect as the basic patent, provided the product has been authorised through the EMA's centralised procedure. Unlike unitary SPCs, which are automatically valid in all countries participating in the unitary patent court, centralised SPCs may be valid in only one or several Member States, depending on the countries mentioned in the SPC application. Purpose of the centralised examination is to simplify the examination process and reduce legal uncertainty.

Analogous to the unitary SPC application, centralised SPC applications must be submitted to the EUIPO within six months of receiving marketing authorisation or after granting the basic patent. Applications may be filed in any official EU language. The application content is similar to that for unitary SPCs but includes a requirement to specify the Member States for which certificates are sought under the centralised procedure. Application fees and possible procedural fees are payable to the EUIPO.

The EUIPO assesses applications for each designated Member State. It's possible that the application may fulfil requirements for some but not all Member States, leading to a mix of positive and negative examination opinions. As with the unitary SPC, substantive examination is performed by the central examination panel, with provisions for filing written observations. The panel issues a binding opinion. If this opinion is positive, the formal granting of the certificates is handled by the competent national authority in each applicable Member State, following their respective national rules and procedures. Member States can only decline issuing a certificate if material circumstances have changed since the centralised application was filed.

Similar opportunities for opposition and appeal exist as for the unitary SPC. However, as separate examination opinions are issued for each Member State to which the application refers, separate proceedings must also be initiated for each opinion.

For centralised SPCs there is no provision for filing a declaration of invalidity at the EUIPO. Instead, such proceedings must occur under the national law of the authority that granted the SPC and the territorial scope of decisions on invalidity is limited to that jurisdiction.

Combined SPC applications

The SPC proposals include a third option, which effectively combines the unitary SPC route with the centralised application. This option exists as not all EU Member States participate in the AUPC. Under the combined application procedure, the SPC applicant must follow procedural routes and opposition and appeal options for each of the two streams, i.e. the unitary SPC route to obtain an SPC for those Member States that have ratified the AUPC, and the centralised non-unitary SPC route to obtain national SPCs for those Member States that have not.

National SPCs

The proposals allow for the continued existence of purely national SPCs in much the same form as currently. The procedure will, however, remain available only for products that a) have not been authorised through the centralised marketing authorisation procedure or b) are protected by a national patent. It is expected that, over time, this route will become largely obsolete.

Examination authority

The EUIPO has been put forward as the central examination authority for both unitary SPC applications and centralised applications. For this, it must create a new SPC division, develop guidelines for practice and appoint Boards of Appeal. It must also set up an examination panel, including qualified examiners sourced from national patent offices or other competent authorities in two Member States. In the composition of the panels geographic balance and workloads will be considered.

Intersection with the EU general pharmaceutical legislation

The SPC proposals were published alongside another major piece of legislative reform: the proposals for revision of the EU general pharmaceutical legislation. The proposals for this intersect with the SPC proposals at several points:

- The 'sunset clause' states that a marketing authorisation ceases to be valid if a medicine is not placed on the Union market within three years of authorisation or if the medicine is no longer actually present for three consecutive years. A marketing authorisation also needs to be renewed after the first five years on the basis of a re-evaluation of the risk-benefit balance. Triggering of the sunset clause or failure to renew the authorisation automatically results in invalidation of the SPC. The current proposal for revision of the legislation intends to abolish both clauses entirely. Conditions relating to market placement will instead become associated with the duration of regulatory protections. While this change may allow SPC protection to persist even if a product is not launched and enable strategic use of the system by innovators to delay generic entry, the conditions for such use are rare. Moreover, new provisions in the legislation may counteract such system manipulation.
- The proposed revisions intend to better balance incentives for innovation with conditions for access and affordability, as well as better direct innovation to areas of greatest unmet medical need. To do so, it is introducing changes to its system of regulatory protections, making their duration conditional upon fulfilment of various criteria, including for market availability. Such changes may shift the relative economic value of different forms of market protection, potentially increasing the importance of SPC protection to innovators. They may also encourage wider market launch and thus incentivise patent holders to apply for SPCs in a greater number of countries, if not already covered by a unitary SPC.
- Changes to the conditions under which a waiver can be obtained from paediatric investigations may result in a very small increase in the number of products eligible for the paediatric SPC extension.
- The revision foresees expansions to both the mandatory and the optional scope for the centralised procedure for marketing authorisation. However, as currently most innovative products are already authorised through this route, this change is expected to have very little impact on the number of products eligible for the unitary or centralised non-unitary SPC routes.
- The Commission intends to introduce a transferable data exclusivity voucher to reward the development of priority antimicrobials. The voucher will extend regulatory protection by 12 months and is available for no more than 10 products over 15 years. This extension is most valuable for products that would otherwise no longer be protected by any other form of market protection, including an SPC, and is therefore of little consequence to the SPC proposals.

Potential impacts

Harmonisation and administrative simplification

One of the primary objectives of the proposals is to reduce divergence in granting decisions among Member States. By introducing a unitary SPC and centralised assessment most differences in decision outcomes would be eliminated, although some inherent differences may persist due to national factors like patent types or marketing authorisations.

The proposals also aim to improve the quality of SPC certificates by centralising assessments and relying on a shared pool of expertise. While this can enhance the rigour of examinations, criteria like geographical balance among examiners could pose challenges in maintaining high standards.

The likelihood of litigation under the new system depends on several factors. While centralisation could lead to higher-quality assessments and less litigation based on erroneous evaluations, the proposals introduce new procedures for opposition, appeal, and invalidation, that may increase the use of legal proceedings and concomitant costs.

Administratively, the new system simplifies the application process for unitary SPCs by allowing a single point of application and payment to the EUIPO. However, for non-unitary SPCs, the situation remains complex as separate examination opinions for each country could lead to parallel opposition and appeal proceedings. The introduction of a procedure for the declaration of invalidity by third parties before the EUIPO might also add complexity to the system and increase litigation.

Cost implications

The Commission has estimated the cost implications of the proposals in an impact assessment. This study has not independently examined the validity of these estimates. According to the Commission, there will be no impact on the EU budget as the system will be self-funded from application fees. The estimated EUR 1.5 million needed to set-up the EUIPO's new functions will be financed from the EUIPO's accumulated budgetary surplus. Recurring annual costs related to administrative processing, examination, appeals, and system maintenance are expected to be around EUR 1.8 million.

Additional costs to applicants from higher application fees would typically be offset by savings on maintenance fees and agent/attorney fees and reduced translation costs, resulting in a net cost saving. However, for applicants seeking SPC protection in a relatively limited number of countries, the new system could increase costs rather than produce savings.

Access to medicines

Access to innovative medicines is to a large extent determined by national market characteristics, such as market size, availability of treatment alternatives and economic factors regarding pricing and reimbursement. These factors lead to strategic decision-making by marketing authorisation holders about where and when to launch a product. It is unclear how intellectual property rights, including SPCs, and regulatory protections factor into this decision making, particularly as these are largely identical in all EU Member States. It is therefore unlikely that current divergence in national practices involving SPCs have played a significant role in the observed unequal access to innovative medicines in the EU. Whilst administrative simplification may be helpful in making the EU a more attractive market as a whole, the introduction of the unitary SPC and the centralised assessment will do little to address underlying market factors. It is therefore not expected that the SPC proposals will significantly impact access to innovative medicines. Proposed revisions to the EU general pharmaceutical legislation may prove more relevant as a way of promoting equitable access to innovative medicines.

Concerning access to generic and biosimilar medicines, the SPC proposals may have some more consequences even though the criteria that determine which products are eligible for some form of SPC protection will remain largely the same. The duration of SPC protection is similarly not affected by the proposals. The main impact that may be expected results from the territorial scope of protection for unitary SPCs. At present generic entry is allowed from the moment the patent and any remaining regulatory protections have expired, even if the reference product remains under SPC protection elsewhere. However, the introduction of the unitary SPC would bring any country that has ratified the AUPC automatically within the territorial scope of protection, including those countries where at present SPC protection is often not sought. This could mean that generic entry remains prohibited even when the reference product is itself not on the market. This may present a risk of further hindering access to medicines in countries where access is already problematic. However, such markets may remain unattractive even for generic manufacturers as long as SPC protection remains in other markets.

The new SPC system would increase the number of opportunities for generic manufacturers to oppose or appeal granting of an SPC. If this results in fewer SPCs being granted, timely access to generic medicines may increase, but the magnitude of this impact is uncertain. A further possible benefit of the

proposed system is that centralised invalidation proceedings will synchronize access to generic medicines among AUPC countries.

Transparency of information

The SPC proposals mandate the creation of public registers of both applications and certificates to enhance transparency. These registers aim to provide open access, enabling third parties to access information without charge. A separate, restricted, database will contain any supporting documentation provided by applicants and third parties. This move towards publicly accessible registers is significant, particularly for generic manufacturers. Currently, obtaining information on SPC status across Member States is cumbersome and not readily available. A centralised register will simplify this process, although some concerns have also been raised about the possible misuse of the register to facilitate the prohibited practice of patent linkage.

Impact on healthcare budgets

The impact of the SPC proposals on Member States' healthcare budgets is closely linked to their effects on access to generic and biosimilar medicines. The proposals could have both positive and negative impacts on such access, depending on various factors. They may improve transparency and legal certainty for generic manufacturers, facilitating market entry. However, the introduction of the unitary SPC could also delay generic entry in some countries. The Commission estimated that this delay could cost countries up to EUR 37 million annually. The Commission suggests these costs could be offset by investments in research and development, but this is uncertain.

Regarding access to innovative medicines, administrative simplification may encourage marketing authorisation holders to enter more markets. If so, this may raise costs to the health system through inclusion of the medicines into the package of reimbursed care. However, improved availability of innovative medicines is generally considered a positive development and national authorities still have the autonomy to decide what treatments they will fund.

Recommendations

A set of recommendations has been developed, focusing narrowly on the unitary SPC and the centralised assessment for SPC applications. Considerations concerning the SPC system more generally were not within the scope of this study. Recommendations were formulated from the perspective of the Pharmaceutical Strategy for Europe, in particular focusing on the strategy's objectives to ensure access to affordable medicines for patients and support competitiveness, innovation and sustainability of the EU's pharmaceutical industry.

The recommendations offered are aimed at Members of the European Parliament to allow them to seek clarification from the Commission on certain points or suggest amendments to the proposals. Specifically, it is recommended:

- To monitor, in negotiations on the proposals for revision of the EU general pharmaceutical legislation, the status of provisions aimed at increasing access to medicines in all Member States. If such provisions are weakened, alternative provisions could be considered linking eligibility for grant of an SPC to marketing obligations.
- To monitor, following the Regulations entering into effect, whether parties that obtain a unitary SPC certificate use this right to block generic access in participating countries where the reference product has not been offered for or placed on the market.
- To assess, based on results from the previous recommendation, the necessity of adding a clause that unitary SPC protection applies only in markets where the holder of the unitary SPC

has offered the product to the market within a specified time of the SPC protection taking effect.

- To review the necessity for the multitude of opposition and appeal procedures available and, where justified, reduce these. In particular, the added value of the central application for declaration of invalidity at the EUIPO should be carefully considered, given that there is already a possibility to invalidate the unitary SPC before the Unified Patent Court.
- To allow applicants to convert an SPC application into a centralised SPC application for those countries where the conditions for a unitary SPC are not fulfilled.
- To request the Commission to update and further explain its estimates for the set-up costs for the EUIPO. Additionally, the Commission together with the EUIPO could outline an action plan for development of the needed capacity at the EUIPO to ensure the continuity and quality of the system, including a risk management plan.
- To request clarity from the Commission on the levels of compensation to NPOs resulting from the transfer of responsibilities to the EUIPO.
- To request further clarification from the European Commission on how it intends to balance assurance of the highest quality standards in the examination with geographic balance.
- To consider whether SPC examiners should be precluded from serving on the Boards of Appeal.
- To request further clarification from the Commission on how it has prepared its cost estimates for applicants, including underlying assumptions about the frequency of use of procedures. If estimates must be revised upwards, carefully consider the impact of this on SMEs.

1. GENERAL INFORMATION

1.1. Background to this study

In the European Union (EU or 'the Union'), medicinal products can be temporarily protected from direct competition by multiple forms of market protection. One of these is the so-called Supplementary Protection Certificate (SPC), which effectively grants the holder an extension of the patent protection by a maximum of 5 years. The conditions for granting of an SPC and the rights conferred by the SPC have been laid down in a European Regulation (Regulation (EC) No 469/2009¹). This Regulation has in recent years been the subject of several evaluative studies, leading to recommendations for its revision. In parallel to these developments, in 2020 the European Commission (EC or 'the Commission') presented a new Action Plan on Intellectual Property to strengthen the EU's economic resilience.

Against this backdrop, on 27 April 2023, the Commission published a set² of proposals for a:

- Regulation on the unitary supplementary protection certificate for medicinal products³ ('the unitary SPC proposal'); and
- Recast of the Regulation on the SPC for medicinal products, introducing a new centralised procedure for the granting of national SPCs⁴ ('the recast proposal'), as well as amendments to the current and remaining national procedure for the grant of national SPCs.

These two proposals are in this report jointly referred to as 'the SPC proposals'. The proposals follow the introduction of the Unitary Patent (UP) and of the Unified Patent Court (UPC) through the Agreement on the Unified Patent Court (AUPC), which entered into force on 1 June 2023. They also intersect with various EU policy and legislative developments in the pharmaceutical space, including the EU Pharmaceutical Strategy⁵ and the revision of the EU general pharmaceutical legislation⁶.

1.2. About this study

This study offers an overview of the content of the SPC proposals and provides insight into their potential impacts on access to medicinal products⁷. The analysis aims to assist Members of the European Parliament in their assessment of the proposed Regulations.

¹ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

² Two further proposals were published that are similar in nature to those here discussed but that specifically deal with plant protection products.

³ Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013, COM(2023) 222.

⁴ Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast), COM(2023) 231.

⁵ The pharmaceutical strategy for Europe was published in 2020 (European Commission, 2020c).

⁶ Proposals for a new Directive and a new Regulation, jointly making up the EU general pharmaceutical legislation, were published on 26 April 2023 (European Parliament & European Council, 2023a, 2023b).

⁷ In the Request for Proposals for this study, the phrase 'access to health technologies' was used. However, health technology is a broader concept that does not align with the scope of protection conferred by an SPC (which applies only to medicinal or plant protection products). Therefore, in the remainder of this report the phrases 'access to medicinal products' and 'access to medicines' have been used instead.

The scope of this analysis covers the potential impact on access to medicines for human use⁸ resulting from the introduction of the newly proposed SPC regime. Aspects that have been excluded from the analysis are:

- Plant protection products: the Commission simultaneously published two parallel SPC proposals pertaining to plant protection products (European Commission Directorate-General for Internal Market, 2023a, 2023b). However, this study focuses only on medicinal products.
- Medical devices or other forms of health technology that do not fall under the scope of protection of the SPC Regulation.
- Other changes to the EU Intellectual Property framework affecting medicines, such as the Proposal for a Regulation on compulsory licensing for crisis management (Directorate-General for Internal Market, 2023)⁹.
- Potential, but as yet unknown, changes to other aspects of the pharmaceutical system, resulting from either EU legislation or from national legislation and policies. Some consideration has been given to changes that have been proposed to the EU general pharmaceutical legislation.

This report principally focuses on changes in the SPC system compared to the present situation, that is: on the introduction of the unitary SPC procedure and the new centralised assessment procedure for the granting of national SPCs. While the already existing national procedure for the grant of national SPCs is retained under the new proposals (but with a much narrower scope of application than in its current format, where it is the only procedure available for the grant of a SPC), this study will discuss the national procedure only to the extent that it is relevant for the purposes of the present report.

1.3. Methodology and limitations

The analysis presented in this paper is based on a conceptual assessment of potential impacts rather than on empirical data, as the SPC proposals have not yet been adopted and implemented. The reasoning has been derived from a literature analysis of the current system of SPCs and various proposed models for a (unified) SPC, as well as position papers, summarised responses to public consultations submitted to the European Commission and relevant legislative proposals. Conversations with a limited number of experts in the field have aided the study team in identifying and interpreting key documentation, but no stakeholder consultation was conducted.

Although the proposals provide a detailed framework for the new SPC system and its implementation, several important uncertainties remain:

- Whether the proposals will undergo further revisions.
- When the finalised Regulations will come into force.
- How the Regulations, including any safeguard provisions, will be interpreted, and implemented.

⁸ Although the Regulations would apply to medicinal products for both human and veterinary use, the impact on veterinary medicinal products has not been explored specifically.

⁹ This proposal provides for the scope of the Union compulsory licence, covering both patents and SPCs. The Union compulsory licence would apply equally to national patents, European patents and European patents with unitary effect and will extend to the SPC “where such protection is granted when the patent expires during the duration period of that compulsory licence. [...] It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent” (Directorate-General for Internal Market, 2023).

- Whether the Regulations will lead to national court proceedings, for instance regarding the division of powers between Member States and the EU.
- Whether the UPC system will encounter legal problems.
- Whether additional Member States will ratify the AUPC.
- What impact recently proposed changes to regulatory protections in the revision of the EU general pharmaceutical legislation would have.
- To what extent pharmaceutical innovators will use the Unitary Patent system and the associated Unitary SPC.
- When the EUIPO will be ready to perform its new duties as outlined in the SPC proposals, including organisational, logistical, and procedural considerations, as well as potential issues with associated computer systems.

All such factors may affect the likelihood, size and even direction of the potential impacts discussed in this paper. Throughout this paper, these factors have been considered to the extent deemed relevant and possible without delving too far into speculation.

It is also worth noting that some of the potential impacts on access to medicines resulting from the introduction of a unitary SPC are not expected for some time, given the start date of the unitary patent¹⁰. It is therefore possible that, during this time, there may be changes in the way medicines are developed, approved, or financed that could impact access to medicines or place SPCs in a different policy context. Such changes have not been considered for this study.

In the absence of underlying empirical data and without further consultation with stakeholders, any assessment of potential impacts presented in this paper solely reflects the opinions and estimations of the study authors.

¹⁰ The unitary patent system entered into force on 1 June 2023. From that point, and for the very large majority of patents, some time will elapse before applications and grants for unitary patents commence. While a unitary SPCs has to be applied for within 6 months of the granting of the relevant marketing authorisation for the medicinal product protected by the basic patent, the SPC itself will not come into force until the end of the legal duration of the basic patent: after 20 years. Impacts on administrative elements and the rigour of assessment may become more apparent prior to this point in time.

2. THE PHARMACEUTICAL SYSTEM IN THE EU

To better understand the role that intellectual property protection, and in particular the SPC, play in the innovation of and access to medicines, it is helpful to briefly reflect on the composition and characteristics of the pharmaceutical value chain that connects between research and the moment a patient is dispensed their medicine.

2.1. Pharmaceutical research and innovation

The development of innovative medicines is a lengthy, complex process involving many parties. It begins with basic research to understand disease mechanisms and identify potential targets for medicines. This research is often done by universities and research institutes and is publicly funded. Once a promising target is identified, compounds that interact with these targets are synthesised or isolated. These compounds undergo further development to optimise their impact. These steps may happen at public organisations but often are done by private companies with large compound libraries and high through-put screening capabilities.

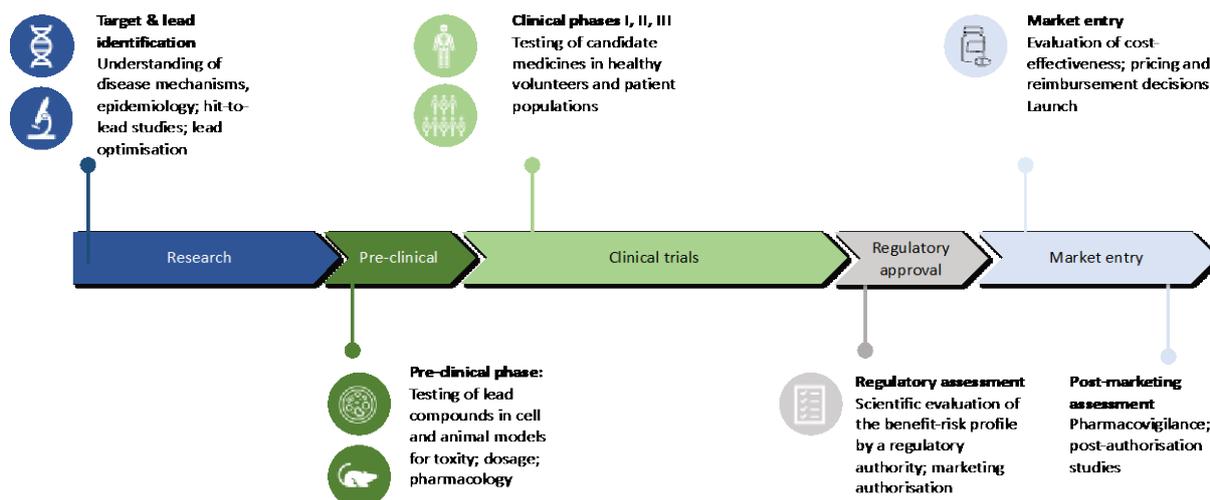
The best lead compounds are then subjected to multiple rounds of development to optimise their interaction with the target and filter out suboptimal leads (“lead optimisation”). Candidate medicines will be examined in cell and animal models to assess their activity against the disease, toxicity, and behaviour in the body. This preclinical development helps determine the suitable form and dosage for human use.

The most resource-intensive and complex stage is testing the medicine in humans, first in healthy volunteers and then in patients. These clinical trials are usually conducted by private research organisations contracted by pharmaceutical companies, but often also involve public (academic) hospitals. It is typically on the basis of the clinical trial results that a regulator decides whether a medicine is sufficiently effective and safe to be admitted onto the market.¹¹ The entire development process, from lead identification to completion of clinical trials, takes around 14 years on average, with an additional 1 to 2 years for assessment and approval (Kalindjian et al., 2022).¹²

¹¹ It is not always be possible, for instance in the case of very rare diseases, to conduct large scale (Phase 3) clinical trials. In such cases, a regulator may decide to (conditionally) approve a medicine on the basis of data generated in the preclinical phase and from early clinical trials.

¹² Shorter timeframes are possible through separate mechanisms for accelerated assessment for products of major interest for public health and therapeutic innovation. For instance, during the COVID-19 pandemic, the timeframe for candidate vaccines was substantially reduced, with clinical trials and marketing approval being finalised within less than 12 months.

Figure 1: Stages of medicinal product development



Source: The authors

While the above describes the typical linear model of medicinal product development, other routes are becoming more common. For instance, new research into already existing medicines may show that these medicines can also be used for treatment of other conditions than those for which the medicine was developed, a process known as repurposing or repositioning. In this case, the initial stages of the development process can be skipped and only (pre-)clinical testing is required. Consequently, the development costs for a repurposed medicine can be substantially lower than for entirely new chemical entities.

2.2. The role of intellectual property

Development of new medicines is very costly, with costs increasing sharply in later stages of the process. The total capitalised costs for development for a single approved medicine are thought to be between EUR 2.2 billion and EUR 3.0 billion (Kalindjian et al., 2022). A large part of these costs is incurred during the clinical trial stage. Although the costs for conducting clinical trials depend strongly on, among other factors, the numbers of patients and research sites involved, estimates put these in the range of EUR 45 million to EUR 210 million (DiMasi et al., 2016; Moore et al., 2020).

Pharmaceutical development also carries a high risk of failure: the large majority of compounds that are identified in the early development stages never make it to market. This risk, linked with the progressively high investments needed at subsequent stages of the development process, means that most new medicines are brought to market by large pharmaceutical companies. Nonetheless, small and medium-sized enterprises (SMEs) play an increasingly important role in the pharmaceutical R&D ecosystem, particularly in discovery, preclinical and early-stage clinical development.¹³

Because of the high investment need and the substantial risk of failure, it is important for product developers that they can recoup their investments through the profitable sale of successfully developed products. Patents and other forms of market protection play a key role in this because they give the company a (temporary) exclusive right to sell their product, free from direct competition.

¹³ For instance, the SME BioNTech SE played a crucial role in the development of a COVID-19 vaccine (in Europe marketed under the name Comirnaty). For this, it entered into a partnership with Pfizer Inc to carry out clinical trials, and to gain access to the manufacturing and commercialisation capabilities of the latter.

Practically all new active substances¹⁴ are under patent protection when they come to market. Patent protection is usually sought during the stages of lead optimisation or preclinical development. However, the holder of the patent need not be the same party that takes the compound through further stages of development: it is not uncommon for pharmaceutical companies to license-in the rights to develop and manufacture a medicine from the patent holder. In this case, the patent holder may receive milestone payments during the development process and, if the product is successfully brought to market, royalties derived from sales. It is thus possible that a patent on a medicine is still held by a university or SME but that the product is produced and sold by a large pharmaceutical company.

Whilst patents are arguably the most important form of intellectual property for pharmaceutical companies, in the EU other forms of market protection exist that have been introduced with the intended aim of incentivising innovation. The following sections provide an overview of all the different forms of market protection that can apply to medicinal products marketed in the EU.

2.2.1. Patents

The primary form of market protection for medicines is the basic patent. A patent protects an innovation and grants the holder a time-limited market exclusionary right in exchange for access to the underlying intellectual property once the patent expires. To obtain a basic patent, an applicant must demonstrate that the invention, which is to solve a technical problem, is new, i.e., not something already known. In addition, it must involve an inventive step, i.e., show that the proposed solution is not obvious to an expert in the field. Eventually, it must be possible to commercially exploit the invention, and the invention must not be something that is on a list of subject matter that is by definition not patentable (such as scientific discoveries). Lastly, the invention must be enabled, meaning that it must be disclosed in such a way that a person skilled in the art (which is the abstract reference person who studies inventions) can carry out the invention without undue burden or inventive skill. For instance, lack of any experimental data in the patent application may (but that will not always be the case) lead to a refusal to grant the patent, because the invention in the patent application is not sufficiently disclosed.

If these criteria are fulfilled, the granted patent provides its holder with exclusion rights, meaning that it can forbid, for instance, the sale or importation of products that contain the invention for a limited period of time. The maximum time limit (term) is 20 years. To keep the patent valid, patent holders must pay annual renewal fees that increase with the running time of the patent. This provides an incentive not to hold patents until the end of their maximum term. For this, and other reasons, patents in most technology fields are often not kept for the full 20 years. However, the specific characteristics of the pharmaceutical market, such as that a product may be granted authorisation to enter the market only towards the later phases of the patent term, make it more likely that the patent is maintained for the full term. In the EU, medicinal products can be protected by either a national or a European patent with or without unitary effect. The following sections provide an overview of these three patent types.

¹⁴ A 'new active substance (NAS)' is: "a chemical, biological or radiopharmaceutical substance not previously authorised in a medicinal product for human use in the EU; an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously authorised in a medicinal product for human use in the EU but differing significantly in properties with regard to safety and/or efficacy from that chemical substance previously authorised; a biological substance previously authorised in a medicinal product for human use in the EU, but differing significantly in properties with regard to safety and/or efficacy which is due to differences in one or a combination of the following: in molecular structure, nature of the source material or manufacturing process; a radiopharmaceutical substance which is a radionuclide, or a ligand not previously authorised in a medicinal product for human use in the EU, or the coupling mechanism to link the molecule and the radionuclide has not been authorised previously in the EU" (European Commission Health and Food Safety Directorate-General, 2019).

a. National patents

National patents are assessed and granted by each Member State separately and need to be maintained – through payment of annual renewal fees – nationally. They can be litigated in national courts.

b. European patents

Since 1978, the European Patent Convention allows the European Patent Office (EPO) to assess and grant a ‘*European patent*’ on behalf of all participating countries. After granting, a European patent falls apart in a ‘bundle’ of national patents that then need to be individually validated in each of the EPO Member States to remain in force.¹⁵ In recent years, the number of applications for European patents on pharmaceuticals has risen sharply: from between 5,000 and 6,000 annually in the period 2013-2016 to over 9,000 in 2021 and 2022 (European Patent Office, 2023).

In 2013, a special form of the European patent was introduced by means of two EU Regulations¹⁶, accompanied by the Agreement on a Unified Patent Court (AUPC).¹⁷ These introduced the so-called *European Patent with unitary effect*, or unitary patent. The unitary patent entered into force on 1 June 2023, together with the AUPC.

Table 1: Types of basic patents for medicinal products in Europe

	Assessment body	Granting body	Geographic scope of patent registration	Payment of costs	Litigation
National patents	National body in Member State	National body in Member State	One Member State	Annual renewal fees paid per country	Court at Member State level
European patent without unitary effect ('European patent')	European Patent Office	Granted by EPO, validated by national body in Member States	In each country individually after a common granting procedure, in up to 39 countries ¹⁸	Annual renewal fees paid per country post grant	Unified Patent Court (unless opted-out) / Court at Member State level
European patent with unitary effect ('unitary patent')	European Patent Office	European Patent Office	Registered in up to 25 Member States ¹⁹ simultaneously	Annual renewal fees paid for all countries in one transaction	Unified Patent Court

Source: The authors based on their knowledge and (EP & C Patent Authorities, 2023; European Commission, 2022).

¹⁵ Art. 2(2) European Patent Convention, <https://new.epo.org/en/legal/epc>.

¹⁶ EU Regulation on implementing enhanced cooperation in the area of the creation of unitary patent protection (Regulation No 1257/2012) and the EU Regulation on implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (Regulation No 1260/2012).

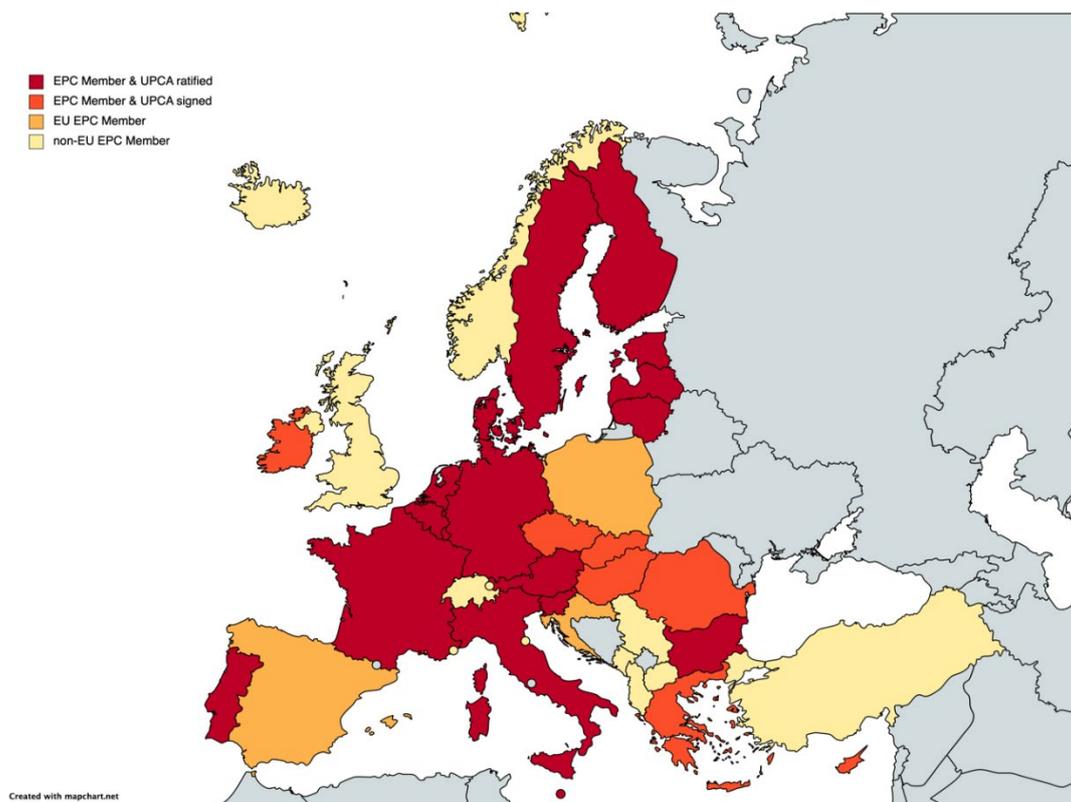
¹⁷ Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1–40.

¹⁸ Currently, these are the 27 European Union Member States plus several other countries (e.g., Norway, Switzerland, and Turkey).

¹⁹ Only in participating Member States. Currently, these are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden. Coverage by the unitary patent also depends on whether the AUPC has been ratified: currently 17 out of 25 countries which are signatories to the AUPC have done so. See: <https://www.epo.org/applying/european/unitary/unitary-patent.html>.

The Commission reasons that the unitary patent will make it possible to obtain patent protection in all Member States party to the AUPC through a single application to the EPO, with the aim to make “access to the patent system easier, less costly and legally secure”, and eliminate the complexity of the current system (European Parliament & European Council, 2012). As the unitary patent procedure came into force during the writing of this study, the success of these aims cannot yet be determined.²⁰ All EU Member States, apart from Croatia and Spain, have signed the AUPC. Out of these 25 countries, at the time of analysis 17 had also already ratified the AUPC.²¹ Figure 2 indicates which Member States have signed, or signed and ratified, the AUPC and which of these countries are also part of the European Patent Convention.

Figure 2: Member States: European Patent Convention and AUPC²²



Source: The authors, based on (European Patent Office, 2022; Unified Patent Court, 2023)

²⁰ According to a statement on the website of the UPC, the “Court has 23 cases, consisting of 6 protective measures (more specifically, 4 applications for provisional measures; 2 applications to preserve evidence), 3 Revocation actions and 14 Infringement actions. The Court also received 236 protective letters.” Statement 29 June 2023, see <https://www.unified-patent-court.org/en/news/communication-7th-upc-administrative-committee-meeting-26-june-2023> (last visited 13 July 2023).

²¹ Signature of an international treaty signifies the intention to comply with the treaty, and is non-binding. Ratification of an international treaty signifies the country in question will be bound by the treaty after national approval is given (procedures for this differ per country) and is binding.

²² EPC Member & AUPC ratified: Austria; Belgium; Bulgaria; Denmark; Estonia; Finland; France; Germany; Italy; Latvia; Lithuania; Luxembourg; Malta; the Netherlands; Portugal; Slovenia; Sweden.

EPC Member & AUPC signed: Cyprus; Czechia; Greece; Hungary; Ireland; Romania; Slovakia.

EU EPC Member: Croatia, Spain, Poland.

Non-EU EPC Member: Albania; Iceland, Liechtenstein; Monaco; Montenegro; North Macedonia; Norway; San Marino; Serbia; Switzerland; Turkey; United Kingdom. Non-EU countries part of the EPC cannot join the UPC or the UP. European patents issued by the EPO need to be ratified in each country individually.

Figure 3 illustrates how a unitary patent procedure progresses: a European patent will be granted by the EPO, and after granting, the applicant can request unitary effect. Once a European patent is granted, the patent has two pathways: as a unitary patent in AUPC countries or, for those Member States which have not ratified the AUPC, validated into the respective Member State²³. There is, therefore, a single European Patent examination procedure (and opposition/appeal procedures) managed by the EPO, which can culminate in the grant of a European patent split into various territorial scopes.

The entry into force for the unitary patent concurs with the start of operations by the Unified Patent Court (UPC), an international court set up to deal with legal infringement and validity claims for unitary (exclusive jurisdiction) and European patents.²⁴ However, the UPC has no jurisdiction over European patents that have been opted-out from unitary effect by the patent holder before any action has already been brought before the UPC.²⁵

The unitary patent is different from the European patent without unitary effect in that the patent will be registered in all participating Member States simultaneously, as opposed to requiring individual Member States to grant or validate the patent. Box 1 summarises the key differences between European patents with and without unitary effect, whilst Figure 3 shows the routes for obtaining a traditional European patent (in grey) or, alternatively, for obtaining a European patent with unitary effect (in blue).

²³ Here the European patent becomes a national patent after grant and needs to be validated into each European Patent Court Member State. Otherwise the patent lapses.

²⁴ Shared jurisdiction with national courts during the transitional period of seven years, which may be extended with another period of seven years (Art.83(1) AUPC.

²⁵ Art. 83(3) AUPC.

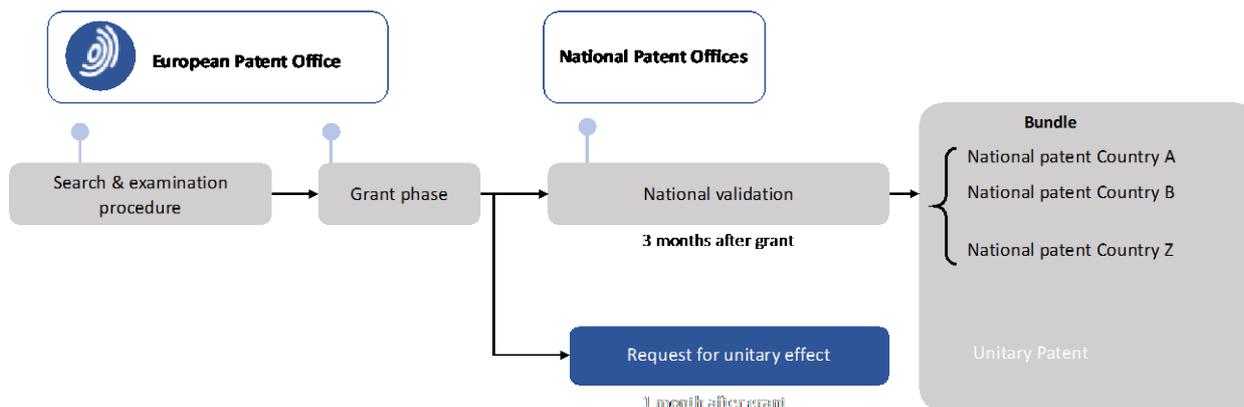
Box 1: Difference between a traditional European patent and a European patent with unitary effect

In line with Art. 2(2) of the European Patent Convention, a traditional European patent, once granted, falls apart in a bundle of national patents. The European patent then becomes a national patent in each of the designated countries and will need to be validated in line with national procedures and requirements. Renewal fees must also be paid at the national level. The European patent system has a centralised examination and grant procedure at the European Patent Office, and there are central Opposition and Appeal proceedings. Decisions by any of these instances affect the European patent for the entire territory of the Member States of the European Patent Convention (currently 39). Invalidity proceedings of a European patent post-grant, and if not already subject to a central Appeal procedure, will need to be litigated at the national court level, as are infringement claims, injunctive relief, etc.

A unitary patent is also a European patent and is filed for in the same way as a traditional European patent. However, after granting of the patent, the applicant may request unitary effect within one month after grant of the European patent. That is why the official denomination is “European Patent with unitary effect” (EPUE). The unitary effect means that the unitary patent becomes subject to a single renewal fee and that it can be revoked in one court action before the Unified Patent Court for the whole of the territory.²⁶ The patent no longer needs to be validated in each country designated in the European patent application, apart from those that do not take part in the enhanced cooperation unitary patent system where national validation will still be required. A unitary patent is subject to the same examination procedure, and central Opposition and Appeal proceedings as a traditional European patent.

Unlike the traditional European patent, a unitary patent can become the subject of central infringement and invalidity claims at the Unified Patent Court (which may issue injunctive relief for the entire territory). This court has exclusive jurisdiction over unitary patents, with the exclusion of national jurisdictions, but only for legal issues which are listed under the exclusive competences in the AUPC (Art. 32 AUPC). Some legal issues, such as compulsory licensing, arguably also entitlement proceedings (who has in fact the rights to the invention claimed in the patent application), and probably also independent claims relating to Standard Essential Patents (SEPs) and FRAND licensing terms, remain at the level of national jurisdictions.

Figure 3: Overview of procedures for obtaining a European patent



Source: The authors. Top = Procedure resulting in a traditional European patent. Bottom = Procedure resulting in European patent with unitary effect (in blue).

²⁶ According to the legal framework upon which the unitary patent system has been built, patents can only have unitary effect in those Member States that have ratified the AUPC (at the time of writing this includes 17 Member States).

2.2.2. Additional forms of market protection

For most other patent-protected innovations, patent expiration marks the point where competition may emerge and, as a result, prices begin to fall.²⁷ Medicines, however, can be protected further by several other forms of market protection offered by the EU legislative framework.

- **Supplementary Protection Certificate (SPC):** SPCs for medicinal products offer patent holders up to five years of additional protection against generic competition after expiration of the basic patent, with a possible one time 'paediatric extension' of six months, subject to compliance with an approved Paediatric Investigation Plan (PIP)(European Commission, 2009; European Parliament & European Council, 2006). The certificate was introduced to compensate for the loss of effective patent protection term incurred between patent filing and regulatory approval (See section 2.1). The SPC is at the heart of this analysis and will be explained in more detail in Chapter 3 of this report.
- **Data exclusivity and market protection:** The current EU general pharmaceutical legislation grants marketing authorisation holders an eight-year period of data exclusivity and a further two years of marketing protection²⁸, starting from the moment of global marketing authorisation²⁹ (European Parliament & European Council, 2004). As long as the product is under data exclusivity, no applicant for another marketing authorisation may refer to the submitted data supporting the regulatory assessment. Regulatory agencies may not validate any application for a generic, hybrid or biosimilar version of the referenced product. After this period, developers of such products may refer to the data to support their own applications, but their products may still not be allowed on the market even after having been authorised by virtue of an additional two years of market protection. A further one year of market protection can be obtained if, during the first eight years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications previously assessed to deliver significant clinical benefits compared to existing therapies.³⁰ This system of consecutive regulatory protections is often referred to by the '8+2+1' formula. In a recent proposal for revision of the EU general pharmaceutical legislation, important changes have been proposed to the duration and conditions for obtaining these forms of protection (see Section 5.2.2).
- **Orphan market exclusivity:** To incentivise the development of new medicines for rare diseases ('orphan medicines'), the European Orphan Regulation offers developers of

²⁷ In other innovation-driven sectors, it is not uncommon even for price reductions to precede patent expiry as a result of competition from other innovations that are not covered by the patent (i.e. that use alternative technologies) or because the natural product life cycle is shorter than the term of the patent. However, for medicines, this is not usually the case.

²⁸ Art. 14(11): "Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies."

²⁹ The Global Marketing Authorisation (GMA) contains the initial authorisation and all variations and extensions thereof, as well as any additional strengths, pharmaceutical forms, administration routes or presentations authorised through separate procedures, including in different Member States within the EU, and under a different name, granted to the holder of the initial authorisation. Where a product is initially authorised nationally and, subsequently, an additional strength, pharmaceutical form, administration route or presentation is authorised through the centralised procedure, this is also part of the same GMA (Article 6(1) second subparagraph of Directive 2001/83/EC).

³⁰ Directive 2001/83/EC additionally allows one year of exclusivity on the data submitted to support authorisation for a new therapeutic indication for a well-established substance, or for a change in classification, provided significant new tests or trials were carried out (Articles 10(5) and 74(a) respectively).

designated orphan medicinal products³¹ a ten-year period of market exclusivity during which the European Medicines Agency (EMA) will not consider any other application for a similar medicine for the same condition, unless considered safer, more effective, or otherwise clinically superior (European Parliament & European Council, 1999)³². The period can be extended by two years if results from all studies agreed in a Paediatric Investigation Plan (PIP) have been submitted (European Parliament & European Council, 2006)³³. If a medicine is approved for use in more than one orphan indication, separate periods of orphan market exclusivity can be granted for each indication. Under the proposed revisions to the EU general pharmaceutical legislation, changes are foreseen also to the duration and conditions for obtaining orphan market exclusivity (see Section 5.2.2).

- **Paediatric SPC extension:** To encourage further research supporting the development of medicines suitably adapted for use in children, the Paediatric Regulation³⁴ obliges pharmaceutical developers to submit a Paediatric Investigation Plan, outlining plans to conduct the necessary studies to assess whether and how the product may be suitable for children use. The PIP is requested by, and must be agreed with, the EMA. The obligation for a PIP may be waived for products where such studies are not deemed relevant or appropriate. In exchange for completing all agreed investigations and making the results available, developers receive a six-month extension of the SPC³⁵. Orphan medicines are excluded from the right to the paediatric SPC extension. Instead, developers of designated orphan medicines for which a PIP has been completed may receive a two-year extension of the orphan market exclusivity, as indicated above. It is, however, still possible to obtain a paediatric SPC extension on a product that has previously been designated as an orphan medicine, if its orphan designation has either expired or been withdrawn.

³¹ In the EU, a medicine can receive a designation as an orphan medicinal product if, after evaluation, it is considered to meet the following criteria: 1) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; 2) the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; 3) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorised, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

³² Art. 8(1): (1) "Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation (EEC) No 2309/93 or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down in Articles 7 and 7a of Directive 65/65/EEC or Article 9(4) of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products(7), and without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product."

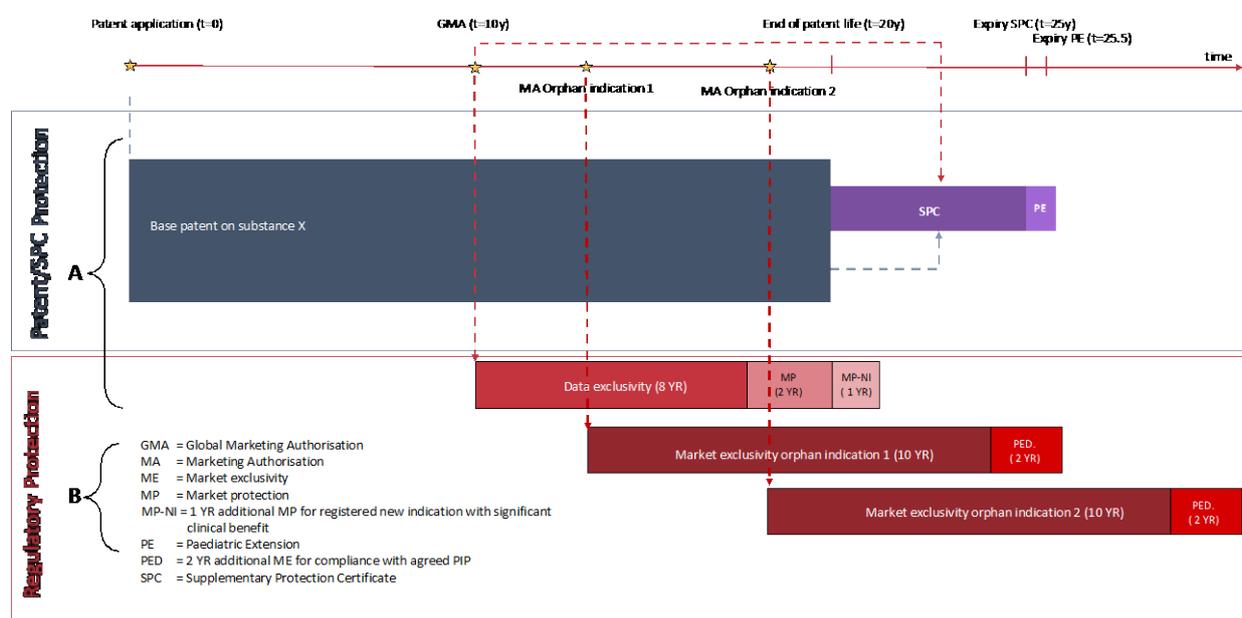
³³ Art. 37: "Where an application for a marketing authorisation is submitted in respect of a medicinal product designated as an orphan medicinal product pursuant to Regulation (EC) No 141/2000 and that application includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, and the statement referred to in Article 28(3) of this Regulation is subsequently included in the marketing authorisation granted, the ten-year period referred to in Article 8(1) of Regulation (EC) No 141/2000 shall be extended to twelve years. The first paragraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned."

³⁴ Regulations (EC) No 1901/2006 and No 1902/2006.

³⁵ Art. 26(3): "For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the supplementary protection certificate ...". Importantly, the grant of the extension is not conditional upon the results of these investigations themselves. Thus, the extension can be granted even if the results show that the medicine is not suitable for paediatric use.

The multitude of protections available in the EU and the ability for some of these to co-exist creates a complex landscape of exclusive rights (Figure 4). It is important to understand, though, that while the different forms of exclusivity complement each other, their scope of protection narrows: the protection provided by the basic patent in the first 20 years has the widest scope, whilst the scope of subsequent SPC protection and regulatory protections is more limited to specific contexts (visualised below by the width of the boxes for each form of protection).

Figure 4: System of intellectual property and regulatory protections on medicinal products in the EU



Source: Adapted from (de Jongh et al., 2018) taking recent case law into account (CJEU C-673/18 – Santen).

2.3. Access to medicinal products

After a medicine has been successfully developed and patented, it cannot immediately be placed on the EU market. Instead, a medicine must go through a sequence of processes and decisions aimed at ensuring their quality, safety, and efficacy³⁶, and bringing the right product to the right person at the right time.

Firstly, all medicines require a marketing authorisation before they can be placed on the market. To obtain a marketing authorisation, pharmaceutical companies must provide clinical evidence and other information to a designated competent authority.³⁷ On the basis of that evidence, the authority evaluates the quality, safety, and efficacy of the product before deciding whether to grant a marketing authorisation. In the EU, there are several pathways for obtaining a marketing authorisation system and the authorisation can apply to one, several, or all Member States (Table 2).

³⁶ Efficacy refers to the capability of a medicine under ideal conditions (controlled), whereas effectiveness refers to the capability of a medicine in normal clinical conditions (not controlled).

³⁷ A competent authority means an organisation that has the legal power to perform a designated function. With regards to the authorisation of medicines in the EU market, this function can be fulfilled by either a national authority or by the European Medicines Agency.

For innovative medicines, by far the most common authorisation route nowadays is the ‘centralised procedure’.³⁸ This route is mandatory for several classes of medicines³⁹, including all oncology medicines, vaccines, orphan medicines, ATMPs⁴⁰ and medicines derived from biotechnology processes, and optional for others⁴¹. Under the centralised procedure, the assessment is performed by the EMA, in consultation with experts, healthcare professionals and patients. The authorisation is valid in all Member States. Currently, the European Commission issues an average of 88 centralised marketing authorisations per year (European Commission, 2023b).

Alternatively, companies may apply for authorisation in one or more Member States through a national procedure. The application is then assessed by a national competent authority rather than by the EMA. A medicine not yet authorised in the EU can be authorised in several Member States simultaneously through the decentralised procedure. An authorisation issued in one Member State can also be recognised in another without the need to repeat the scientific assessment by use of the Mutual Recognition Procedure. This process can be repeated to obtain authorisation in multiple Member States. Most generic and non-prescription medicines in the EU are assessed and authorised through a national route.

Table 2: Marketing authorisation pathways in the EU

Source: European Medicines Agency⁴²

	Assessment / Scientific evaluation	Granting body	Product scope	Geographic scope
Centralised marketing authorisation (CMA)	European Medicines Agency	European Commission	Mandatory for some products; optional for others	All EU Member States, Iceland, Norway, and Lichtenstein
Decentralised marketing authorisation	Reference Member State ⁴³	National body	Optional for products which do not require CMA and have not yet been authorised in any Member State	Concerned Member States
Mutual recognition	Recognition of a pre-existing national marketing authorisation by one or more EU countries ⁴⁴	National body	Optional for products which do not require CMA	Reference Member State + Concerned Member States
National marketing authorisation	National body	National body	Optional for products which do not require CMA	One Member State

³⁸ Authorisation of medicines. European Medicines Agency. <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines#national-authorisation-procedures-section>.

³⁹ Annex to Regulation 726/2004. These include products derived from biotechnology; advanced therapy medicinal products; medicinal products for human use which contain an active substance authorised in the Union after 20 May 2004 and which are intended for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune disfunctions, and viral diseases; and orphan medicinal products.

⁴⁰ Advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes, tissues or cells.

⁴¹ Art. 3(2): “2. Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the Community in accordance with the provisions of this Regulation, if: (a) the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at Community level.”

⁴² <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines>.

⁴³ Under decentralised marketing authorisation, an application for marketing authorisation is submitted simultaneously in several EU countries (‘Concerned Member States’), one being chosen as the ‘Reference Member State’.

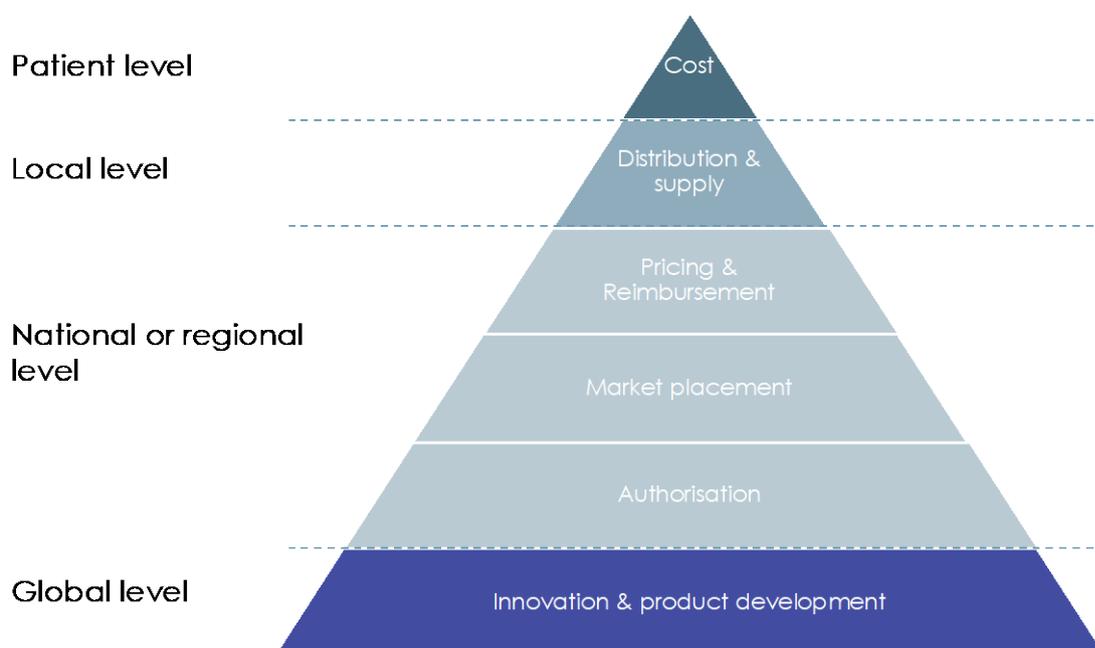
⁴⁴ This requires the product to have received marketing authorisation in at least one Member State.

Once a marketing authorisation has been obtained, the marketing authorisation holder (MAH) can decide to launch a product on the market. This still, however, does not mean that the product will immediately become available in each EU country. Medicines are still subject to pricing and reimbursement decisions, which may involve processes to evaluate their cost-effectiveness. These processes differ in each country but are often made up of an assessment of relative effectiveness and cost (Health Technology Assessment, HTA), price setting, and negotiations with insurers or procurement agencies. The HTA system aims to assess a medicine's added value and, in the context of rationalisation of health expenditures, enable the public system to prioritise medicines that offer the best value for money. This assessment can lead to the conclusion that, despite having been authorised, a medicine is not reimbursed in a particular country. This can create access problems for patients in that country. In addition, commercial strategies and profit considerations can result in delays for some countries, or even instances where a product is never placed on a particular market.

Lastly, products that are on the market and reimbursed by the national system may still not always reach patients. This could be due to prescribing behaviours, procurement contracting or insufficient availability (e.g., due to shortages). It is, thus, important to note that access to medicines is influenced by many processes, behaviours, and factors at different levels (Figure 5).

The combination of these factors leads to a situation where, across the Union, there are large differences in the availability of medicines and the length of time for products to reach patients between different Member States (Newton et al., 2022). These factors are largely independent from intellectual property rights and regular protections, although there is undeniably a link between the existence of market protections on the one hand and price setting and competition on the other.

Figure 5: Factors influencing access to medicines



Source: (De Jongh et al., 2021).

Even with the current movement in the direction of greater cooperation and harmonisation between EU Member States, a division of responsibility and powers between Member States and the Union for certain steps in the above pharmaceutical chain will remain. While IP is an important component of protecting and encouraging innovation, its effects on access to medicines always needs to be considered in the context of such other factors.

3. THE SPC SYSTEM: PAST, PRESENT AND FUTURE

3.1. The Supplementary Protection Certificate

The normal period for a basic patent for medicinal products is 20 years. However, as noted previously, medicines cannot be immediately placed on the market after patent applications have been filed or, in most cases, even after patents have been granted because of the extensive testing requirements to demonstrate effectiveness and safety for marketing authorisation. This creates an effective “loss” of patent protection. To address this loss, SPCs were introduced in the European Union in 1992 through Council Regulation (EEC) No 1768/92, which has since been replaced by Regulation (EC) No 469/200945 (‘the SPC Regulation’).

The SPC Regulation reasons that the loss of time between the start of patent protection and obtaining marketing authorisation results in a total period of effective protection that is insufficient to cover the research investment made by pharmaceutical companies. It thus sets out to provide ‘adequate effective protection’ by ensuring that a patent holder can enjoy a maximum of 15 years of exclusivity once the product obtains marketing authorisation. Patent holders can receive up to 5.5 years⁴⁶ of extra protection in the form of the SPC, providing them with longer exclusivity rights on their product and delaying competitors from creating generic versions of the same product (European Commission, 2023b; Hu et al., 2020). SPC durations are capped to reflect other interests at stake, such as public health. An SPC takes effect immediately after the end of the term of the basic patent. It can apply to medicinal products (human and veterinary) as well as to plant protection products.

A supplementary protection certificate is a *sui generis* intellectual property right that extends by up to 5 years the effect of a patent in a Member State (European Commission, 2020a).

The stated objectives of the SPC system include encouraging R&D in new active ingredients at a global level, making the EU an attractive location for R&D (preventing ‘delocalisation’ outside the EU), creating a homogenous SPC system, and harmonising the internal market (Barton, 2022; European Commission, 2020a).

There are some exemptions to SPC rights, such as the Bolar exemption⁴⁷ and the SPC manufacturing waiver⁴⁸. SPCs fall under the scope of compulsory licensing (Directorate-General for Internal Market, 2023).

3.1.1. Features of the existing SPC system

The SPC Regulation lays down the conditions for obtaining an SPC, the rights and obligations it confers on the holder of the SPC and the processes that govern the application, assessment and granting as well as the procedures that exist for opposing and invalidating SPCs. The Regulation also specifies the respective responsibilities of all parties that play a part in the SPC system. Further clarification on the

⁴⁵ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

⁴⁶ Up to 5 years of ‘regular’ SPC extension plus six months paediatric extension.

⁴⁷ The Bolar exemption allows manufacturers to prepare generic products for clinical trials prior to the expiration of the term of the basic patent or the SPC of the innovator product.

⁴⁸ The SPC manufacturing waiver allows generic products to be manufactured during the SPC term for export (outside of the EU) or storing purposes, under certain circumstances.

interpretation of the SPC Regulation has come from case law by national courts and the Court of Justice of the European Union (CJEU).

a. Product eligibility

The SPC Regulation lays down the general conditions determining whether a medicinal product⁴⁹ can be protected by an SPC. To be eligible, a product⁵⁰:

- Must be protected by a basic patent that is in force;
- Must have been granted a marketing authorisation somewhere in the EU;
- Must not have been protected by an SPC before; and
- the marketing authorisation must be the first authorisation in the EU to place the product on the market as a medicinal product.⁵¹

b. SPC duration

The duration of an SPC is calculated by establishing the time between the patent filing date and the marketing authorisation date, minus five years.⁵² The remaining time provides the duration of the SPC, subject to a maximum of five years. This means that SPCs are not available for products where the difference between the patent filing date and the marketing authorisation date is less than 5 years. The average duration of SPC protection has been estimated at 3.5 years (European Commission, 2020a, 2023b).

c. Applications and assessment

Although the conditions for granting of an SPC have been laid down in an EU Regulation that applies equally in all EU Member States, the assessment and process of granting of an SPC thus far have been national decisions. Applications are submitted to a national patent office, or similar authority, in each of the Member States where protection is sought. Applications have to be submitted within six months of the marketing authorisation date, or if the marketing authorisation is issued prior to the grant of the patent, within six months after the grant of the patent. Each national patent office will award a certificate or reject the application based on their assessment of the application, and by applying and interpreting the provisions of the SPC Regulation, which has become part of domestic law. If awarded, the SPC is only valid within that Member State. Figure 6 summarises the different processes and procedures that make up the current SPC system.

d. Opposition, appeal and invalidation of an SPC

Under the current SPC system, Member States have several further legal proceedings at their disposal to contest decisions of the national patent offices or similar authorities. Some of these exist in certain Member States, but not in others. Under the current system, there is therefore a lack of harmonisation as to the means of redress for both applicants and third parties.

⁴⁹ A medicinal product is defined by the SPC regulation (Article 1) as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals.'

⁵⁰ As defined in Art. 3(1) of Regulation 469/2009.

⁵¹ For a concise overview of what those requirements exactly entail, see (de Jongh et al., 2018).

⁵² Art. 13(1): "The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years."

During the examination of an application, many EU jurisdictions allow for the submission of so-called written observations. This means that, prior to grant, any third party can make written submissions about the (un)desirability of an SPC being granted in a specific case. National patent offices are not under an obligation, though, to take those observations into account in their assessment of the SPC application.

No EU Member State jurisdiction currently provides for an opposition procedure,⁵³ which would prototypically be a procedure where, once the SPC has been granted, any third party can oppose the grant of an SPC within a certain period of time. Although Denmark provides for an administrative re-examination procedure that can be requested by any third party, it has emphasised that this is not formally an opposition procedure (Mondrup Pedersen & Justesen, 2021).

For cases where the SPC application is rejected, applicants can, depending on the national jurisdiction, file an internal administrative appeal at the national patent office. Against any such decision of an Appeal Board within the national patent office, an appeal is possible to the courts (for both the applicant and the national patent office). In some jurisdictions, no internal administrative appeal exists, or it can be forfeited, which then leaves the option to appeal the decision to refuse the grant of an SPC to the competent national courts. From thereon, the case might make its way into appeal, and where necessary, a referral to the CJEU for a preliminary ruling in accordance with the TFEU⁵⁴. This is an *ex parte* procedure⁵⁵, limited to the SPC applicant and the national patent office.

For cases where the SPC is granted, any third party can try to invalidate it in the national courts, typically by means of a separate invalidation action. In a situation where a third party would have been sued for patent or SPC infringement, a counterclaim for invalidity may also be filed. From thereon, once again, the case can move into appeal and where necessary also to the CJEU. These are typically *inter partes*⁵⁶ proceedings.

As the commercial stakes are typically very high with medicinal products, appeal proceedings are very common. Nonetheless, most cases do not rise to the level of the CJEU and proceedings here are an exception.

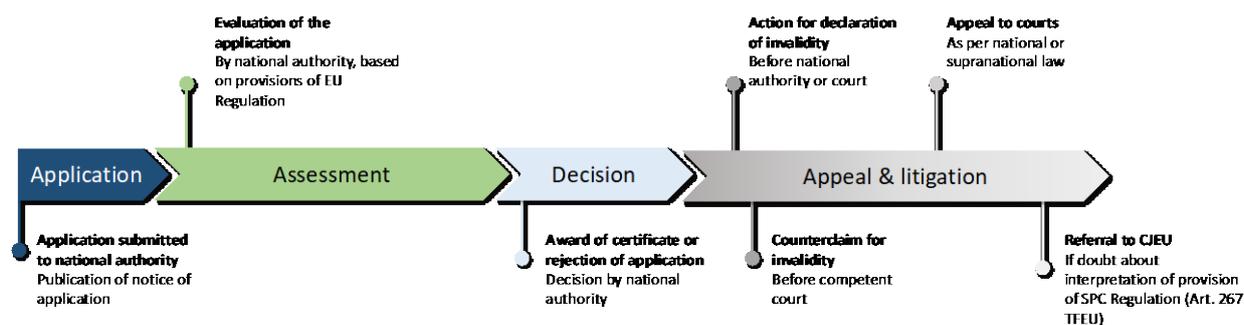
⁵³ In line with Art. 19(2) SPC Regulation 469/2009, according to which "Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded."

⁵⁴ Art. 267 of the TFEU: "The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning: (a) the interpretation of the Treaties; (b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union. Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon. Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court. If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay."

⁵⁵ In an 'ex parte' proceeding, the case is limited between an applicant on the side, and the authority responsible for taking a decision on the other side.

⁵⁶ 'Inter partes' proceedings are those where the applicant and third interested parties (such as, for instance, alleged patent or SPC infringers) are involved and present arguments.

Figure 6: Current processes and procedures available in the SPC system



Source: The authors, based on (European Commission, 2009).

3.1.2. National differences in the SPC system

Despite the SPC Regulation setting out uniform eligibility criteria for the granting of SPCs, Regulations 469/2009 and 1610/96 still allow for a degree of national interpretation⁵⁷ (European Commission, 2020a). This is a common feature of European law, as harmonised legal provisions always need to be applied by a national court to a specific set of facts, and in doing so, slightly varying interpretations of the same statutory text will inevitably occur. It is the role of the CJEU to provide further clarity, where necessary, on the intended interpretation.

As a result of these differing national interpretations and practices, elements of the application of the SPC Regulation have remained divergent across Member States. For example:

- Some Member States have granted SPCs where others have refused identical applications⁵⁸ (this was the case for 26% of medicinal products between 2004 and 2014 (European Commission, 2020a)).
- SPCs have been granted with a different scope by different Member States.
- SPC expiry dates vary across Member States, seen for 80% of products which had SPC protection approved between 2004 and 2014 (Mejer, 2017). Different expiry dates were attributable to Member States issuing different decisions in 26% of products, while in 58% of products it was due to the authorisation data reported in the applications (Mejer, 2017).
- The share of pending or rejected SPC applications varies substantially between Member States (European Commission, 2020a).

Further variations concerning the interpretation of the SPC Regulation can be found around the type of products that are covered. For instance, countries like Denmark, France, Italy, Poland, Portugal, Spain, and the United Kingdom (UK) do not consider medical devices to fall within the jurisdiction of SPC Regulation, while Germany and the Netherlands do. Third-party observations are allowed in some countries but not in others: at least 18 Member States do, but others do not (e.g., Greece and Lithuania) (European Commission, 2023b; Piachaud-Moustakis, 2023a).

The transparency of SPC systems also differs by Member State: a 2020 survey of National Patent Offices found that publication of information can take between a couple of days to over a year, and only 14 offices publish information in English in addition to their official language (European Commission,

⁵⁷ National authorities may still grant SPCs without verifying that the substantive conditions laid down in paragraphs (c) and (d) of Article 3 of the SPC Regulation.

⁵⁸ For example, the combination Zetia (ezetimibe) plus Lipitor (atorvastatin) was rejected for an SPC in France, while it was granted an SPC in Belgium (Piachaud-Moustakis, 2023b).

2023b). About half do not provide online access to SPC application documents (European Commission, 2023b).

Other factors also contribute to a fragmented SPC system. A public consultation held by the European Commission in 2017 saw stakeholders raise differences in granting procedures; in availability and/or training of SPC examiners; in the length of examination; in outcomes from examinations; and in outcomes of court proceedings (European Commission, 2020a; Max Planck Institute for Innovation and Competition, 2022; Piachaud-Moustakis, 2023b). The complexity of the system in the EU (e.g., the legislation and case law, difficulties interpreting the SPC Regulation, and the absence of uniform expertise in the national agencies) as well as the increasing complexity of products (e.g., biotechnology) further contribute to divergence (European Commission, 2020a; Papadopoulou, 2018, 2022).

The Commission has stated that fragmentation in the system results in higher levels of bureaucracy, reduction in innovation and availability of new medicines and limit access to affordable generics due to uncertainties for generic manufacturers (European Commission, 2020a). The underlying argument is that fragmentation in the system can create additional costs, arising from redundant granting procedures, monitoring, litigation etc. This would affect patent holders (especially SMEs), start-ups, and generics makers as well as public authorities, and in doing so undermine the efficiency of the SPC system.

Further concerns relate to the lack of unitary SPC protection for the new unitary patent (see Section 2.2.10), as the current system would only allow for patent term extension through national SPCs; the suboptimal transparency of SPC information in the current system; and the high costs and administrative burden for SPC applicants (European Commission, 2022). In the absence of a unitary SPC, patent holders would only be able to extend a unitary patent by applying for national certificates in each Member State, a time and resource intensive activity.

There has been a considerable amount of case law around the SPC Regulation at the European Court of Justice to reflect on the interpretation of aspects of the Regulation. This has already led to somewhat of a convergence of practices and has reduced uncertainty (European Commission, 2023c). Nonetheless, the Commission sees scope for further reducing this divergence through the introduction of a unitary certificate and a centralised assessment procedure (see Chapter 4).

3.1.3. Trends in SPC applications in the European Union

Data on SPC applications show three trends, starting from their first use in the early 1990s to now⁵⁹.

1. *An increase in the total number of SPC applications across the EU Member States.* The total number of annual SPC applications across all the EU Member States increased between 1994 and 2013, from nearly 507 in 1994 to 1,518 in 2013 (Mejer, 2017). In 2021, about 1,459 SPC applications were filed in the EU-27 (European Commission, 2023b). This increase is, in part, attributable to the increased number of Member States over this period and the establishment of the EMA introducing centralised marketing authorisations. Evidence suggests that products with central authorisation often have a broader geographic SPC protection scope (i.e., protection in more countries) than nationally approved medicines: on average, products with a centralised marketing authorisation have a 70% larger geographic scope than medicines approved nationally (Mejer, 2017).

⁵⁹ The data presented in this section may include both SPCs for medicinal products and plant protection products. However, the majority of the SPCS are for medicines: the European Commission estimates nearly eight times more SPCs are applied and granted for medicinal products than for PPPs (European Commission, 2023a).

2. *Variations between the number of applications across Member States.* Since 1993, between 25 and 81 SPC applications were filed annually per Member State (European Commission, 2023b; Mejer, 2017). Between 2014 and 2021, the highest number of applications was seen in Germany (an average 81 of per year), followed by Italy (76), Spain (76) and France (75), while smaller jurisdictions, such as Croatia (32) and Malta (25), had a much lower average number of applications (European Commission, 2023b).
3. *An increase in the number of new medicinal products obtaining an SPC.* The proportion of new medicinal products obtaining an SPC in at least one Member State increased from 75% in the 1990s to 86% in 2017 (European Commission, 2020a). SPC applications covering the same product were submitted in an average of 10 EU Member States at the end of the 1990s, increasing to 20 Member States in 2014 (European Commission, 2023b; Mejer, 2017).

3.1.4. Evaluation of the SPC system and rationale for change

Based on the aforementioned observations, as well as findings from impact assessments (European Commission, 2020a, 2023b) and inputs provided by stakeholders (European Commission, 2022), the Commission has concluded that the national level administration and granting of SPCs is the main shortcoming of the system, undermining its effectiveness and efficiency and resulting in duplication of work and high costs (European Commission, 2020a, 2022, 2023c).

Additionally, it argues that the current SPC system, under which the territorial scope of an SPC is limited nationally, is misaligned with the unitary patent system, which grants patent titles with unitary effect covering a territory extending far beyond a single Member State (European Commission, 2023c)(European Commission, 2022; Max Planck Institute for Innovation and Competition, 2022). The Commission aims to address these issues by introducing a unitary SPC and amending the SPC Regulation in other parts. The next chapter describes the proposals that the Commission has been brought forward for this purpose.

4. PROPOSAL FOR A NEW SPC SYSTEM IN THE EU

4.1. Reasoning and options

In light of the identified issues around the current SPC regime (Section 3.1.2) and the need to offer a unitary SPC to accompany the unitary patent, the Commission has extensively explored the possibility of introducing a unitary SPC. In 2022 the Commission published a call for evidence for an impact assessment on this issue (European Commission, 2022). Its aims were to:

- Increase legal certainty around the procedure for granting SPCs,
- Provide unitary SPC protection to accompany unitary patents,
- Make SPC-related information more transparent, clear, and accessible,
- Reduce the cost and burden of obtaining/maintaining SPC protection.

For this, the Commission developed five policy options (European Commission, 2023c). These increase in the level of action or responsibility placed at EU level and in the degree of mandatory issuance of SPCs.

Table 3 presents each of these options and their identified drawbacks or advantages.

Table 3: Policy options considered for a unitary SPC

	Description (European Commission, 2023b)	Drawbacks and advantages
Option 0	No policy change	
Option 1	Guidelines for the application of the current SPC regimes. This option would provide common guidelines/recommendations to national patent offices (NPOs) on the application of the SPC Regulation, building on their experience and the case law of the CJEU. These guidelines would also recommend common rules for the publication and accessibility of SPC information in national registers.	As these guidelines would have been non-binding, adherence levels could vary and, thus, this option may not fully solve the issues identified around the current regime.
Option 2	Mutual recognition of national decisions. This would enable applicants to file an SPC application with a designated NPO, known as the reference office, whose decision would be recognised by all other NPOs.	A lack of predictability - the designated NPO may not apply the regulations as other countries would, possibly encouraging applicants to engage in 'forum shopping'.
Option 3	Centralised filing and examination of SPC applications, resulting in a nonbinding opinion. This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether or not to grant an SPC. NPOs could follow this opinion or, alternatively, conduct their own examination. Therefore, the decision on granting SPC protection would be kept at the national level. Only holders of a European patent – and, for medicinal products, of a centralised marketing authorisation – could use this system.	The non-binding nature of option 3 allows NPOs to re-examine the centralised decision, thus may result in a system where fragmentation and divergence could persist.
Option 4	Centralised filing and examination of SPC applications, resulting in a binding opinion. This is identical to option 3, but NPOs would have to follow the opinion. Therefore, while decisions on granting SPC protection would still be taken by national offices, the outcome of these decisions would be determined by a central authority.	Selected as basis for the centralised SPC procedure. Together with option 5, it combines the advantages of a 'one-stop-shop' SPC procedure with obtaining unitary SPC protection in countries where the corresponding unitary patent takes effect, and a <i>de facto</i> uniform title by virtue of the binding

	Description (European Commission, 2023b)	Drawbacks and advantages
		Examination Opinion for those Member States where there is no unitary patent protection.
Option 5	A 'unitary SPC' complementing the unitary patent. The central authority, in addition to examining applications, would grant a 'unitary SPC' to applicants with a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (initially 17) Member States party to the UPCA.	Selected as basis for the 2023 unitary SPC proposal because, together with option 4 (in case of a combined procedure with the centralised SPC procedure), it combines the advantages of a 'one-stop-shop' SPC procedure with obtaining unitary SPC protection in countries where the corresponding unitary patent takes effects, and a de facto uniform title by virtue of the binding Examination Opinion for those Member States where there is no unitary patent protection.

Source: Adapted from (European Commission, 2023c) Note: The descriptions are taken verbatim from the SPC proposals. UPCA refers to the Agreement on the Unified Patent Court, in other places of this report referred to as the AUPC.

4.2. Preferred options

The model outlined by the Commission for the revision to the SPC system combines options 4 and 5 (Table 4): a centralised procedure resulting in the grant of national SPCs in some or all Member States (option 4), and a unitary procedure resulting in the grant of a single SPC in the Member States where the basic unitary patent is in place (option 5). An application combining these two options will also be possible. The result of this is the grant of a unitary SPC in AUPC Member States and of national SPCs in other Member States. The current route of granting purely national SPCs will also remain for nationally authorised products. However, when a product is granted a centralised marketing authorisation, the applicant only has the choice between the unitary SPC application or the centralised procedure but not the national procedure.

Thus, with the proposed additions, there will effectively be four routes to obtaining an SPC in the EU. The main characteristics of each of these routes are explained in the following sections.

Table 4: Overview of proposed procedures for obtaining an SPC

	Assessment body	Granting body	Type of SPC	Geographic scope
Centralised procedure	EUIPO	National Patent Offices	Binding opinion from EUIPO; National SPCs granted	Member States designated in the application
Unitary procedure	EUIPO	EUIPO	One SPC granted; immediately applicable	All Member States covered by unitary patent
Combined procedure	EUIPO	EUIPO + National Patent Offices	One SPC granted for AUPC Member States; Binding opinion from EUIPO; National SPCs granted for other Member States	All Member States covered by unitary patent + any other Member States designated in the application
National procedure	National Patent Office	National Patent Office	Purely national SPC	Member State where the certificate was granted

Source: (European Commission, 2023c)

4.3. The unitary SPC

4.3.1. Characteristics of the unitary SPC

For the introduction of a unitary SPC for medicinal products, the Commission relies on the legal basis of Article 118 of the Treaty on the Functioning of the European Union (TFEU).⁶⁰ The proposal requires that the basic patent⁶¹ is a unitary patent and the marketing authorisation invoked for the SPC application must be one granted under the EMA centralised procedure. The requirement for an underlying unitary patent ensures that the patent's claims are identical for all Member States. By contrast, traditional European patents fall apart in a bundle of national patents that, once granted, may have slightly different scope of protection in different Member States, whilst national patents have a purely national territorial scope (see Section 2.2.1). Both traditional European patents and national patents consequently can lead to some degree of variation. For that reason, it is not desirable to accept them as the basic patent for a unitary SPC. Relying on these would also increase the workload of patent examiners to check whether the product is patented in all applicable Member States.

The requirement for a centralised marketing authorisation also differs from the current situation, which accepts national authorisations as a base for the application. However, allowing a unitary SPC to be based on national authorisations would complicate the examination of applications and could run into issues arising from potential differences between the individual national authorisations.

Beyond these two specific requirements, the conditions that must be fulfilled for granting of a unitary SPC are the same under this proposal as under the current Regulation, meaning that the product cannot already have been the subject of a certificate, nor of a unitary certificate, and that the

⁶⁰ Art. 118: "In the context of the establishment and functioning of the internal market, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements. The Council, acting in accordance with a special legislative procedure, shall by means of regulations establish language arrangements for the European intellectual property rights. The Council shall act unanimously after consulting the European Parliament."

⁶¹ Basic patent means a (unitary) patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a unitary certificate. See Art. 2(5) (European Commission, 2023c) and Art. 2(3) (European Commission Directorate-General for Internal Market, 2023c).

authorisation on which the certificate is granted is the first authorisation to place the product on the market as a medicinal product (Box 2).

As with the unitary patent, a unitary SPC would be valid with unitary title in all countries that participate in the AUPC.

Box 2: Conditions for obtaining a unitary SPC

"1. A unitary certificate shall be granted by the [European Patent] Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled:

- (a) the product is protected by that basic patent in force;
- (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;
- (c) the product has not already been the subject of a certificate, nor of a unitary certificate;
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State⁶². Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable." (European Commission, 2023c)

4.3.2. Application procedure

Applicants must apply for a unitary SPC to the EU Intellectual Property Office (EUIPO) within six months of receiving marketing authorisation for the product in question, or, where the authorisation is granted before unitary effect is attributed to the basic patent, within six months after unitary effect has been attributed to the basic patent (the role of the EUIPO is discussed further in Section 4.7). The proposal foresees that applicants can file an application for a unitary SPC in any official EU language. As the amount of text in an SPC application is small, and some of this text would not require translation, the costs related to translation are expected to be small (European Commission, 2023c).

Applicants must pay an application fee, and possibly other fees (e.g., for appeals, or for renewals), to the EUIPO (European Commission, 2023c). A proportion of these fees may be passed to the National Patent Offices of the Member States, as appropriate, and to the National Patent Offices that participated in the substantive examination (European Commission, 2023c). The fees to be charged by the EUIPO will be published in an implementing act.

4.3.3. Assessment procedure

The assessment of the application for a unitary SPC follows a multi-step process (See Figure 7) (European Commission, 2023c). The first step will be for the EUIPO to assess the formal admissibility of the unitary SPC application. This means an assessment of whether the application received fulfils the

⁶² This provision is new compared to the current SPC Regulation (EC) No 469/2009. It is as yet unclear what the impacts of this new provision may be and, in line with the agreed scope of this study, the issue has here not been further explored.

basic criteria and that the application fee has been paid⁶³. If these criteria are not fulfilled, the EUIPO will request applicants to fulfil the requirements within a certain deadline. If that deadline is not met, the application will be automatically rejected. Applicants can appeal a rejection.⁶⁴ If the EUIPO finds that the criteria for formal admissibility of the application have been fulfilled, the application will be published by the EUIPO in a register.

The second step will be for a panel to perform a substantive examination, resulting in the publication of an examination opinion. This examination will focus on the conditions for eligibility for a unitary (SPC). During the examination period, third parties (including Member States) can provide written observations on the validity of a unitary SPC application.⁶⁵ Observations must be submitted within 3 months of publication of the application in the register and can be filed in any EU official language (currently 24).⁶⁶ The examination panel is under no obligation to take these written observations into account, but can take inspiration from them prior to deciding on the outcome of the SPC application. Where the results of this examination deem the conditions have been met, a positive examination opinion will be issued⁶⁷. Where it is deemed these have not been met, a negative examination opinion will be issued. The examination opinion will be translated into the official languages of all designated Member States.⁶⁸

At present, the receiving and assessment of applications is done by the relevant national authority in each Member State. As previously noted, aspects of how this is done may vary from country to country (see Section 3.1.2). By transferring these responsibilities to the EUIPO and a central examination panel, the Commission hopes that administrative complexity and variation between countries can be reduced. To this end, the EUIPO must develop guidelines for the conduct of the assessment and apply these consistently to each application.

⁶³ Art. 11: Examination of the admissibility of an application for a unitary certificate

“1. The Office shall examine the following:

(a) whether the application for a unitary certificate complies with Article 9;

(b) whether the application complies with Article 8;

(c) whether the application fee referred to in Article 31(1) has been paid within the prescribed period.

2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.

3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.

4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application for a unitary certificate.”

⁶⁴ Art. 28: “Any party to proceedings under this Regulation, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.”

⁶⁵ Art. 14(1): “Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates, in one or more of the Member States in which the basic patent has unitary effect.”

⁶⁶ Art. 14(4): “Any observations by a third party shall be submitted in writing in one of the official languages of the Union and state the grounds on which they are based.”

⁶⁷ Art. 13: “(1) The Office shall assess the application on the basis of all the conditions in Article 3(1), for all Member States in which the basic patent has unitary effect. (2). Where the application for a unitary certificate and the product to which it relates comply with Article 3(1) for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant. (3). Where the application for a unitary certificate and the product to which it relates does not comply with Article 3(1) in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.”

⁶⁸ Art. 13(4): “The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.”

4.3.4. Opposition and appeal

The proposal recognises the need for stakeholders to be able to oppose the application and assessment during the assessment process. Therefore, any third party will be able to initiate an opposition procedure during the two months after the publication of a positive examination opinion. Opposition procedures can only be started if the third party believes the conditions for eligibility have not been met. An opposition fee is levied on these applications.

An opposition panel will be set up to examine the opposition application. Examiners from national offices may be involved in these opposition procedures, but these cannot be the same examiners from the application assessment. An opposition may result in the examination opinion being amended (for instance, that the examination opinion should now state that not all conditions for the grant of an SPC have been fulfilled), or the opposition could be rejected. Decisions on opposition applications will be taken within 6 months unless the case is deemed complex.

Once a decision in the opposition procedure has been taken, there are potentially three different appeals procedures possible at the central level (this is to say, against the examination opinion of the EUIPO, as possibly amended during opposition). Further legal proceedings with the UPC are possible only if the SPC has been granted.

After the opposition procedure has been finalised, any of the parties involved in the proceedings may, if they feel adversely affected by the decision, file an appeal with the Boards of Appeal at the EUIPO within two months.

Any decision taken by the Boards of Appeal at the EUIPO may be subject to a further appeal at the European General Court⁶⁹. Where the requirements have been met, an appeal to the judgement of the European General Court will be possible to the CJEU.

These appeals will also be available to the applicant if the examination opinion of the EUIPO is negative, i.e., it proposes to refuse the grant of a unitary SPC.

4.3.5. Decision on granting

After the completion of the assessment of either a unitary SPC application, and once the time limits for, or the procedures for, opposition and appeal have expired / have been finalised, the EUIPO must implement the examination opinion by either granting a unitary certificate or rejecting the application, as applicable⁷⁰ (European Commission, 2023c). The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States in which the basic patent has unitary effect⁷¹. The duration of a unitary SPC will be calculated in the same manner as a national SPC (see Section 3.1.1).

Under the proposal, the decision to grant or reject an application must be published in a public register. This register must serve as a single access point to provide information on applications, granted certificates, and their status/expiry. For a fee, parties can request an extract from the register. This register should be available in all official EU languages. A separate database will be kept by the EUIPO to assist with administration of application, accessing necessary information for any proceedings,

⁶⁹ A feature common to all administrative decisions taken by EU agencies.

⁷⁰ Art. 18: "Grant of a unitary certificate or rejection of the application for a unitary certificate. After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

(a) where the examination opinion is positive, the Office shall grant a unitary certificate;

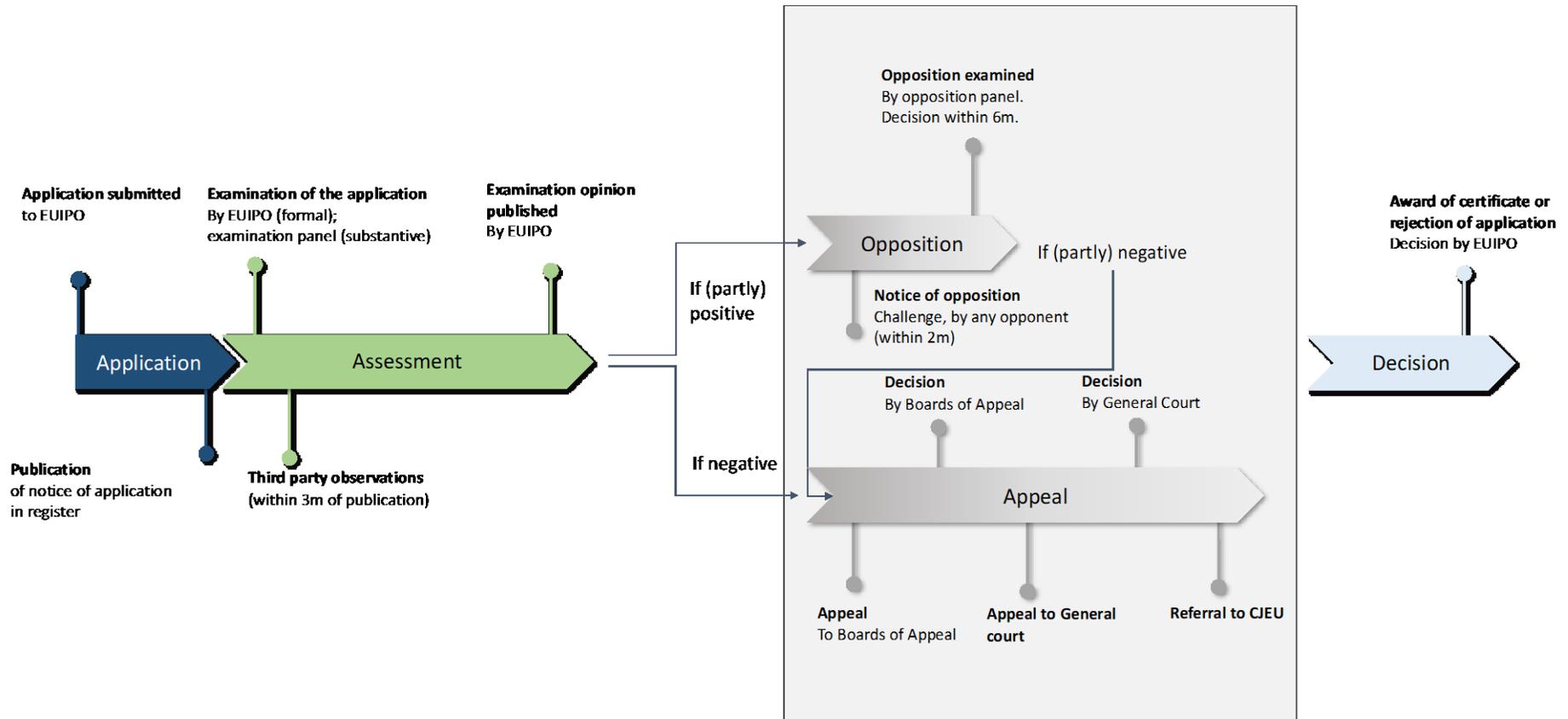
(b) where the examination opinion is negative, the Office shall reject the application for a unitary certificate."

⁷¹ Art. 5(1).

communication with applicants and third parties, and producing reports and statistics. The proposal does not provide further detail on what information will be in the database.

The full procedure from the initial application for a unitary SPC until the point of a decision on whether to grant the certificate, including the possibilities for opposition and appeal prior to this decision, has been summarised in Figure 7.

Figure 7: Proposed procedure for obtaining a unitary SPC



Source: The authors, based on (European Commission, 2023c).

4.3.6. Post-grant invalidation and appeal

If all options for opposition and appeal at the level of the examination opinion are exhausted, and if a decision has been made to grant a unitary SPC, third parties can start an action for a declaration of invalidity before the EUIPO (European Commission, 2023c).⁷² This action will challenge the validity of the certificate granted by the EUIPO and was, according to the Commission, introduced to ensure consistency with the Charter of Fundamental Rights.⁷³

Invalidity of a unitary certificate can be established if, a) the certificate was not granted in line with the requirements or, b) the term of the basic patent has lapsed (e.g., due to unpaid renewal fees) before its lawful term expires, or c) the basic patent is revoked or limited such that the eligibility criteria are no longer fulfilled or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.⁷⁴ One of these three conditions must exist in at least one Member State for an application for declaration of invalidity to be filed. A related filing fee will need to be paid. Examiners from national offices may be involved in these invalidity procedures. If the application is considered admissible, it will be published in the register. Then, if an examination of this application reveals one of the three conditions mentioned above is met, the unitary certificate can be declared invalid.

The EUIPO's decision on a declaration of invalidity can be appealed within two months at the Boards of Appeal. The decision made by the Boards of Appeal can, in turn, be appealed at the European General Court within two months, and a final appeal can be raised at the European Court of Justice.

The proposal provides yet another means to invalidate a unitary SPC by filing a counterclaim for invalidity before the competent jurisdiction. In the case of the unitary SPC this is expected to be the UPC⁷⁵. The proposal dictates that either the interested party or the court shall inform the EUIPO of the

⁷² Art. 23: "(1) Any person may file with the Office an application for a declaration of invalidity of a unitary certificate. (2) An application for a declaration of invalidity may only be filed on the grounds that one or more of the conditions set out in Article 22 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect."

⁷³ The Charter of Fundamental Rights of the European Union covers the personal freedoms and rights EU citizens have. EU institutions and Member States must respect the rights in the Charter.

⁷⁴ Art. 22: "The unitary certificate shall be invalid in any of the following events: (a) the certificate was granted contrary to Article 3; (b) the basic patent has lapsed before its lawful term expires; (c) the basic patent is revoked or limited to the extent that the product for which the unitary certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation."

⁷⁵ Art. 24 Unitary SPC proposal: "(1). A counterclaim for a declaration of invalidity may only be based on the grounds for invalidity set out in Article 22. (2). The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the Office relating to the same subject matter and cause of action and involving the same parties has already become final. (3). If the counterclaim is brought in a legal action to which the holder of the unitary certificate is not already a party, that holder shall be informed thereof and may be joined as a party to the action in accordance with the conditions applicable before the competent court. (4). The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the Office of the date on which the counterclaim was filed. The Office shall record that information in the Register. If an application for a declaration of invalidity of the unitary certificate had already been filed before the Office before the counterclaim was filed, the court shall be informed thereof by the Office and stay the proceedings until the decision on the application is final or the application is withdrawn. (5). Where the competent court of a Member State has given a judgment which has become final on a counterclaim for a declaration of invalidity of a unitary certificate, a copy of the judgment shall be sent to the Office without delay, either by the court or by any of the parties to the national proceedings. The Office or any other interested party may request information about such transmission. The Office shall mention the judgment in the Register and shall take the necessary measures to comply with its operative part. (6). The competent court hearing a counterclaim for a declaration of invalidity may stay the proceedings on application by the holder of a unitary certificate and after hearing the other parties and may request the defendant to submit an application for a declaration of invalidity to the Office within a time limit which it shall determine. If the application is not made within the time limit, the proceedings

counterclaim. If a declaration for invalidity relating to the same SPC has already been filed at the EUIPO, the competent court shall stay proceedings until the EUIPO has taken a decision. On application of the holder of the unitary SPC, the court can stay proceedings regarding the counterclaim for invalidity and request the defendant (the party who filed the counterclaim for invalidity) to file for a declaration of invalidity of the unitary SPC at the EUIPO within a time limit the court shall determine. Appeals against any decisions made by the competent court will be possible in line with the appeal rules applicable to the law of the competent court. In case of the UPC, that would imply an appeal to the Unified Patent Court of Appeal, and where there would be a yet unanswered question of European law to be interpreted, the case may be referred to the CJEU.

4.4. Centralised national (non-unitary) SPC

4.4.1. Characteristics of the centralised SPC

As not all medicinal products will be protected by a unitary patent, the proposals for the new SPC system also foresee in a new option for a centralised, yet non-unitary, SPC. The legal basis for this resides in Article 114 of the TFEU⁷⁶ (European Commission, 2023c).

Under this option, an application for an SPC can be filed centrally by invoking a European patent without unitary effect as the basic patent, if the product has been authorised under the centralised marketing authorisation procedure. As with the unitary SPC, the choice for a European patent as the basic patent is motivated by a desire to facilitate the examination process and reduce legal uncertainty compared to a situation whereby national patents can be invoked. The traditional European patent still allows for some degree of national variation in the claims, as noted previously. To avoid complications arising from this, in principle, it would have been possible to introduce a requirement that in a centralised SPC application all claims of the basic European patent must be identical for all Member States in which the SPC is sought. However, in an explanation of the specific provisions of the proposal, the Commission indicates that cases where there are two or more sets of claims from different Member States are quite rare and therefore considers such a requirement unnecessary.

As with the unitary SPC, the use of the centralised marketing authorisation is similarly based on an intent to minimise the examination workload and avoid complications arising from variations between national marketing authorisations, including language issues.

Whereas a unitary SPC will be valid in all AUPC countries, a centralised certificate will be valid in one or more Member States, depending on which are mentioned in the SPC application. Under the centralised non-unitary SPC application, the grant of the SPC will be done by the national patent offices. Crucially, though, this must be based on a binding opinion produced by the EUIPO.

4.4.2. Application procedure

Centralised applications for an SPC certificate must be lodged with the EUIPO⁷⁷ This must be done within six months of receiving marketing authorisation for the product in question, or, where the authorisation is granted before the basic patent, within six months after granting of the basic patent.

shall continue; the counterclaim shall be deemed withdrawn. Where the competent court of a Member State stays the proceedings it may order provisional and protective measures for the duration of the stay."

⁷⁶ Art. 114(1): "[...] The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market."

⁷⁷ Art. 20(3): "A centralised application shall be lodged with the European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office')."

As with the unitary SPC, the application may be filed in any official EU language. The contents of the application are the same as for a unitary SPC, except for the additional requirement that the application indicates in which Member States certificates are sought under the centralised procedure.

Application fees and possible other procedural fees must be paid to the EUIPO, analogous to the provisions in the unitary SPC proposal. Since the implementing act under which the amount of fees payable will be specified has not yet been developed, it is unknown how the costs for a centralised application will compare to those for a unitary SPC. Since the centralised procedure results in the grant of national certificates, any annual renewal fees must be paid directly to the national authority that has granted the national certificate.

4.4.3. Assessment procedure

Once a centralised application has been received, the EUIPO will assess the application for each of the designated Member States. Unlike with the unitary SPC application, it is possible that the outcome of this is that the application fulfils the requirement in some but not all Member States designated in the application. In this case, the EUIPO may issue a positive examination opinion for those countries where the requirements are met and a negative opinion in those where this is not the case.

In all other respects, the process for examination of the application is the same as that for the unitary SPC, with the substantive examination performed by the hereto designated examination panel. This is also true for the possibility to file written observations.

4.4.4. Opposition and appeal

The initiation of an opposition after the publication of the positive examination opinion is allowed during the examination of a centralised application in the same way as for unitary SPC applications. The substantial difference though, is, that any opposition filed must be done so for each positive examination opinion produced. Indeed, under the centralised non-unitary SPC application, the EUIPO must produce a separate examination opinion for each Member State. It is very well possible that for some Member States, all requirements will be fulfilled, whilst this may not have been the case for one or more other member states. This could, for instance, be the case if the product has already been the subject of an earlier marketing authorisation in one Member State⁷⁸, but not in another.

For each of those examination opinions that have become subject to an opposition, a decision taken in opposition can become the subject of further appeals (with the Boards of Appeal at the EUIPO, the European General Court, and where applicable the CJEU), identical to those for the unitary SPC procedure (see Section 4.3.4). The only difference is that those procedures will need to be followed for each of the separate examination opinions individually. As a consequence, it is possible that multiple oppositions and appeals may ensue from a centralised non-unitary SPC application.

4.4.5. Decision on granting

One of the main differences between the unitary SPC application and an application lodged through the centralised procedure arises at the moment where the EUIPO has issued a positive examination opinion. This opinion is transmitted (including translations) to the competent national authority in each of the Member States designated in the application. As the EUIPO's opinion is binding, those national authorities are required to grant a national certificate in accordance with applicable national

⁷⁸ As this would be in conflict with Art. 3(d): "A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application, all of the following conditions are fulfilled: [...] (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product." (European Commission Directorate-General for Internal Market, 2023c)

rules and procedures. The only possibility for Member States to decline issuing a certificate is if “material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions [...]”. A negative examination opinion by the EUIPO is equally binding and Member States must therefore also reject a national certificate.

Although the centralised procedure results in issuance of national certificates, any extensions to the duration of those certificates (see Section 2.2.2) must again be filed centrally with the EUIPO.

4.4.6. Post-grant invalidation and appeal

Since the grant of non-unitary SPCs is legally done by national patent offices, any post-grant invalidation proceedings must take place under the possibilities provided by the national law of the authority that granted or refused the SPC, and by what is provided for in the SPC recast proposal. This means that, for centralised non-unitary SPC procedures, there is no possibility to file for a declaration of invalidity at the EUIPO. Instead, there is the possibility to file for a declaration of invalidity with the national competent court, or with a competent national authority, if the national law provides for this. Any judgement rendered by the national body may become subject to further appeals available under the laws governing that jurisdiction.

To the extent that there may be an issue of interpretation of European law, for instance a provision regarding the SPC regulation, there is the further possibility for a referral to the CJEU. The territorial scope of decisions relating to a declaration of invalidity will be limited to the jurisdiction of the Member State for which the national SPC has been granted.

Even though not explicitly stated in the proposals, to the extent allowed under the national law of the competent national jurisdiction, there will additionally be the possibility to file a counterclaim for invalidity of any nationally granted SPC⁷⁹ at the national competent court. Where in the unitary SPC proposal proceedings in the counterclaim for invalidity may (have to) be stayed pending a case for declaration of invalidity at the EUIPO (see Section 4.3.6), for nationally granted SPCs any provision to stay proceedings in a counterclaim for invalidity must be decided under the law applicable to the national court deciding the case at hand.

4.5. Combined application

The SPC proposals include a third option, which effectively combines the unitary SPC route with the centralised application (European Commission Directorate-General for Internal Market, 2023c). This option exists as not all EU Member States participate in the AUPC and can be used in cases where there is 1) a unitary patent in effect in AUPC participating countries and 2) a traditional European patent, without unitary effect, in other Member States. As with the two routes it combines, this option requires the existence of a centralised marketing authorisation.

Under the combined application procedure, the SPC applicant must follow procedural routes and opposition and appeal options for each of the two streams, i.e. the unitary SPC route to obtain an SPC for those Member States that have ratified the AUPC (see Section 4.3), and the centralised non-unitary SPC route to obtain national SPCs for those Member States that have not (see Section 4.4).⁸⁰

⁷⁹ Thus including SPCs granted after having proceeded through the centralised assessment as their formal granting has been a national responsibility.

⁸⁰ Art. 39: “(2) The combined application shall undergo a single centralised examination procedure as well as a single opposition or appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application. (3) The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the

The Commission intends for the combined application to follow the common procedures outlined in the previous sections, with a single examination procedure as well as a single opposition and appeal procedure.

One may expect that, unless all Member States join the AUPC, the combined application will become the new norm.

4.6. National SPCs

The proposed recast of the SPC Regulation allows for the continued existence of purely national SPCs, without centralised filing and assessment, in much the same form as it currently exists. The procedure will, however, remain available only for products that a) have not been authorised through the centralised marketing authorisation procedure or b) are protected by a national patent. It is expected that, if an application fulfils the requirements for the centralised SPC procedure, any national application for a certificate filed with a competent national authority is rejected by that authority. It is expected that with the new SPC options available and a potentially further increase in the number of innovative products that are covered by a centralised authorisation (see Section 5.2.3), this route will become largely obsolete.

4.7. Examination authority

As discussed in the preceding sections, the proposal puts forward the EUIPO as the central examination authority for both unitary SPC applications and centralised applications (and, by extension, combined applications), herein supported by national offices. Other options considered included a virtual authority comprising SPC experts from NPOs of Member States, the European Patent Office, the European Medicines Agency, or a mutual recognition procedure implemented by NPOs (European Commission, 2022, 2023b).

The choice for the EUIPO is not entirely self-evident as the agency currently deals with trademarks and designs, but not with patents or SPCs. To implement its new responsibilities, the EUIPO will thus need to set up a new SPC division and develop guidelines for practice (European Commission, 2023c). It will also need to appoint dedicated Boards of Appeal. Although survey results showed minimal support among originator and generic companies for designating the EUIPO as the central examination and granting authority, the Commission's rationale for this selection is based on the EUIPO's existing status as an EU agency and its integration into the EU legal framework (European Commission, 2023b).

To support the examination process, the EUIPO must set up an examination panel, consisting of a member of the new EUIPO SPC Division and two qualified examiners. These examiners would be sourced from national patent offices or other competent authorities in two different Member States. The EUIPO will appoint any competent national authority, which will then designate (an) examiner(s) to participate. Competent national authorities can be appointed as participating offices for five years, with a possible extension of a further five years. According to the proposal, examination panels will take geographic balance and workloads into account in determining its composition. While recognising that the number of competent and qualified SPC examiners in national patent offices is limited, the proposal justifies this staffing choice by referring to the relatively low numbers of SPC applications in a given year (less than 100) (European Commission, 2023c). The proposal also states that suitable criteria around qualification and conflicts of interested will need to be in place for the selection of specific examiners.

combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.”

The proposal furthermore will require the EUIPO to annually publish an overview of its SPC-related work. This would need to include the number of examination, opposition, appeal, and invalidity procedures, and which competent national authority participated in each.

5. REVISIONS OF THE EU PHARMACEUTICAL LEGISLATIVE FRAMEWORK

5.1. The EU pharmaceutical legislative framework

The SPC Regulation is part of a wider framework of EU legislation. This framework consists of a set of legislative acts that govern various aspects of the pharmaceutical market. The mandate for the EU to act in this space is derived from Article 168 of the TFEU, which makes matters of public health a competence shared between the EU and its Member States (EUR-Lex, 2008). Member States retain full autonomy over the organisation and financing of health care⁸¹, while EU action “shall be directed towards improving public health, preventing physical and mental illness and diseases and obviating sources of danger to physical and mental health”.

The TFEU gives the EU strong competences⁸² to adopt “measures setting high standards of quality and safety for medicinal products and devices for medical use”. These competences underpin a set of legislative acts that cover, among other areas, the conduct of clinical trials; the assessment and authorisation of medicinal products; manufacturing and distribution of medicinal products; packaging and labelling; pharmacovigilance; and health technology assessment. The framework also includes specialised legislation concerning medicines for treatment of rare diseases and for children that include incentives to stimulate research and development.

In 2016, the Council of the European Union requested the Commission to prepare an overview of existing EU legislative instruments and related incentives within the pharmaceutical framework to analyse their impacts on innovation and availability and accessibility of medicines, and to develop ways to redress the balance in the system (Council of the European Union, 2016). Following this request, evaluations were conducted of the orphan and paediatric regulations, the SPC regulation and, most recently, the EU general pharmaceutical legislation. Together, these evaluations have highlighted various shortcomings in and challenges to the current system. These include issues of inequitable access to medicines, insufficient innovation in areas of unmet medical need, and a need to future-proof the regulatory framework to cope with medical, scientific and technological advances.

On 25 November 2020, the Commission adopted a new Pharmaceutical Strategy for Europe (European Commission, 2020b, pp. 5–6). The strategy aims to:

- Foster patient access to innovative and affordable medicines and fulfil unmet medical needs;
- Support the competitiveness and innovative capacity of the European pharmaceutical industry;
- Develop EU’s open strategic autonomy and ensure robust supply chains, including in times of crisis;
- Ensure a strong EU voice on the global stage.

⁸¹ Art. 168(7): “Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.”

⁸² Art. 168 (4c): “By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: [...] (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.”

It highlights a need for legislative changes that are aimed at directing more innovation to areas of unmet need whilst placing greater obligations on product developers to ensure affordability and availability of products that benefit from innovation incentives. It calls for changes of the regulatory framework for assessment and authorisation of medicines to accelerate access.

Following a process of stakeholder consultations and preparation of an impact assessment, on 26 April 2023 the Commission published its proposal for a revision of the EU general pharmaceutical legislation. Similar to the current arrangement, the proposed revision will consist of two legislative proposals:

- A new Directive:
 - repealing and replacing Directive 2001/83/EC and Directive 2009/35/EC; and
 - incorporating relevant parts of the Paediatric Regulation (EC) No 1901/2006.
- A new Regulation:
 - repealing and replacing Regulation (EC) No 726/2004;
 - repealing and replacing the Orphan Regulation (EC) No 141/2000; and
 - repealing and incorporating relevant parts of the Paediatric Regulation (EC) No 1902/2006

The previously separate regulations for orphan and paediatric medicines will thus become incorporated into the new legislation to simplify the framework and increase coherence.

Box 3: Objectives of the proposed EU general pharmaceutical legislation

General objectives

- Guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients;
- Harmonise the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States.

Specific objectives

- Make sure all patients across the EU have timely and equitable access to safe, effective, and affordable medicines;
- Enhance security of supply and ensure medicines are always available to patients, regardless of where they live in the EU;
- Offer an attractive innovation- and competitiveness friendly environment for research, development, and production of medicines in Europe;
- Make medicines more environmentally sustainable.

The proposal is pending approval by the European Parliament and will likely undergo further revisions before it can take effect. It is as yet unknown what the finalised legislative text will look like or when this will enter into force and take effect.

5.2. Intersection between the EU pharmaceutical legislation and the SPC Regulation

The current proposal for the revision of the EU general pharmaceutical legislation is ambitious and foresees rather significant changes to the current regulatory framework. It contains a number of provisions that are relevant to consider in the context of the SPC proposals. Given the important consequences these changes could have for the earning potential of pharmaceutical companies, the

proposal is expected to be the subject of intense debate and lobbying. It is therefore not certain that all of the proposed revisions will be implemented as presented. The analysis in the following sections on this chapter is based solely on the current proposal and does not speculate on what changes may still be introduced.

5.2.1. Abolishment of the renewal and sunset clauses

The ‘sunset clause’ is a provision in the EU general pharmaceutical legislation that states that a marketing authorisation ceases to be valid if a medicine is not placed on the Union market within three years of authorisation⁸³ or if the medicine is no longer actually present for three consecutive years⁸⁴ (European Parliament & European Council, 2004). Likewise, a marketing authorisation needs to be renewed after five years on the basis of a re-evaluation of the risk-benefit balance⁸⁵. Once renewed, the authorisation becomes valid for an unlimited period.⁸⁶ Since the validity of an SPC is conditional upon the existence of a valid marketing authorisation, triggering of the sunset clause or failure to renew the authorisation results in automatic invalidation of the SPC.

The current proposal for revision of the EU general pharmaceutical legislation intends to abolish both the renewal and the sunset clauses entirely to “avoid unnecessary duplication and a burden on Marketing Authorisation Holders and regulators” (European Parliament & European Council, 2023b).⁸⁷ Instead, a marketing authorisation shall become valid indefinitely, unless this is limited to five years on the basis of a scientific opinion concerning the safety of the product.⁸⁸ Conditions relating to market placement will no longer be linked to the validity of the marketing authorisation but instead will become associated with the duration of regulatory protections (see Section 5.2.2).

The abolishment of the renewal and sunset clauses could, at least in theory, have repercussions for the availability of medicinal products through its intersection with the SPC system. Currently, if a marketing authorisation holder fails to meet the requirements for market placement or maintaining the product’s availability, the resulting triggering of the sunset clause will immediately lift SPC protection and permit other companies to fill the gap in the market. The proposed changes, however, would allow the SPC protection to remain in place even if the marketing authorisation holder does not enter the market or withdraws its product. Generic products would thus continue to be barred from entering the market whilst the SPC remains in effect, even if the reference product is not marketed (anymore) anywhere in the EU.

⁸³ Regulation (EC) No 726/2004, Art. 14(4): “Any authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the authorising Member State shall cease to be valid”. For centrally authorised medicines, the condition for market placement is considered fulfilled if the product is placed on the market of even a single EU country.

⁸⁴ Regulation (EC) No 726/2004, Art. 14(5): “When an authorised product previously placed on the market in the authorising Member State is no longer actually present on the market for a period of three consecutive years, the authorisation for that product shall cease to be valid.”

⁸⁵ Regulation (EC) No 726/2004, Art. 14(1): “Without prejudice to paragraphs 4, 5 and 7 a marketing authorisation shall be valid for five years.” Art. 14(2): “The marketing authorization may be renewed after five years on the basis of a re-evaluation by the Agency of the risk-benefit balance.

⁸⁶ Regulation (EC) No 726/2004, Art.14(3): “Once renewed, the marketing authorization shall be valid for an unlimited period, unless the Commission decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, to proceed with one additional five-year renewal in accordance with paragraph 2”.

⁸⁷ “Among the measures to reduce the regulatory burden are the abolishment of the renewal and the sunset clause. The simplification of the structure of the scientific committees at the EMA should also reduce the regulatory burden for companies and simplify their interactions with the EMA.” See p. 20, (European Parliament & European Council, 2023b).

⁸⁸ Art. 17(1): “[...] a marketing authorisation for a medicinal product shall be valid for an unlimited period”. Art. 17(2): “By way of derogation from paragraph 1, the Commission may decide when granting an authorisation, on the basis of a scientific opinion by the Agency concerning the safety of the medicinal product, to limit the validity of the marketing authorisation to five years.”

The abolishment of the sunset clause appears to have been fuelled, at least in part, by the observation that it has not been effective as a mechanism for stimulating broad market launch. The current clause only requires launch in a single EU market within three years of granting of the marketing authorisation. It neither prescribes how many additional markets need to be served, nor does it specify a timeframe for further launches. As such, the requirement is easily met and does little to encourage launch in commercially less attractive markets. Both under the current SPC system and under the newly proposed system, validity of an SPC depends on the existence of a marketing authorisation but not on actual market placement. As such, removal of this aspect of the sunset clause may have little to no impact on the functioning of the SPC system.

Potentially more impactful is removal of the stipulation that the marketing authorisation will be invalidated if the medicine has not been marketed for more than three years. In theory, manufacturers of innovative medicines could use this to their advantage if they also have a newer, still patent-protected, product in their portfolio that is under SPC protection and authorised for the same indication as an older product. If they withdraw the older product from the market but maintain its marketing authorisation, the continued existence of the SPC will prevent generic competition until the end of the SPC's lifetime whilst under the current sunset clause this SPC protection would be lifted immediately. Since the original product has also been withdrawn from the market, patients must rely on the newer product, effectively giving its authorisation holder access to a captive market. Crucially, though, this hypothetical situation is based on a rather narrow set of conditions:

- The older product has more than three years of SPC protection left at the time the newer product is authorised, and the SPC is the last form of protection to apply;
- The newer product is still under some form of market protection, most likely patent protection, with a duration that exceeds that of the older product;
- The newer product is a full therapeutic substitute for the older product;
- Authorisations on the older and newer product are held by the same party;
- The party has no interest in further commercialisation of the older product.

It is hard to predict how often this situation could occur. However, it requires a combination of factors several of which are already rather rare individually.⁸⁹

Whilst market withdrawal is an important cause of unavailability of medicines, most product withdrawals concern older products for which all forms of market protection have long expired (de Jongh et al., 2021). Importantly, the proposal for revision of the EU pharmaceutical legislation also contains new provisions to protect security of supply. In case of a market withdrawal, a marketing authorisation holder is required to declare the reasons for the withdrawal and provide the EMA with information on the impact of the withdrawal on patients who are already being treated. If the product is deemed critical, authorisation holders will be obliged to offer the authorisation for transfer to a third party before withdrawal⁹⁰ (European Parliament & European Council, 2023b). This obligation would likely counteract such strategic use of the system.

⁸⁹ For instance, as stated in Section 3.1.1b, the average duration of SPC protection is just 3.5 years.

⁹⁰ Art. 24(4): "Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a critical medicinal product, the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third party that has declared its intention to place that critical medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC]." (European Parliament & European Council, 2023b).

5.2.2. Setting conditions on access to regulatory protections

One of the main objectives of the revision of the EU general pharmaceutical legislation is to address current inequities in the availability of medicines across the EU. As discussed in Section 2.3, there are multiple factors that influence access to medicines, of which many are linked to differences in the size and characteristics of national markets. The EU does not have competency to intervene in national systems for decision-making on pricing and reimbursement of medicines, nor can it oblige marketing authorisation holders to operate in specific markets. It can, however, incentivise market launch by setting conditions on access to regulatory protection incentives offered by the EU legislative framework.

a. Modulating regulatory data exclusivity and market protection

As discussed in Section 2.2.2, the current EU general pharmaceutical legislation offers developers of innovative medicines regulatory protection in the form of 8 years of data exclusivity and up to 3 years additional market protection (the '8+2+1' system). The proposed revisions to the legislation foresee substantial changes to this system. The impact assessment for the development of the revision of the EU general pharmaceutical legislation explored several options for modulating the duration of regulatory protection and setting additional obligations (Table 5)(European Commission, 2023a). The options focused on dividing the regulatory protection period into a standard part and a conditional part, with conditions aimed at incentivising innovation in areas of greatest need, improving the generation of evidence and achieving more equitable access.

Table 5: Options considered for modulating regulatory protection

Elements	Option A	Option B	Option C
Standard regulation protection	8 years DP + 2 years MP	6 years DE + 2 years MP	6 years DE + 2 years MP
Conditional regulatory protection	+1 year DE for UMN +6 months DE for comparative trials + 6 months DE if placed on market in all Member States within 6 years of the authorisation	+2 years for UMN +2 years MP for medicines with no return on investment	+ 1 year for UMN + 6 months for comparative trials + 2 years (or 1) DE if placed on all EU markets within 2 years of authorisation and appropriately and continuously supplied
Additional obligations		Obligation to place a centrally authorised medicine on the market in the majority of Member States (small markets included) within 5 years	
DE = data exclusivity; MP = market protection; UMN = Unmet Medical Need;			

The current proposal for the revision is modelled most closely after Option C but with some changes. It foresees in a standard data protection period of six years from the date of granting of the (initial)

marketing authorisation (European Parliament & European Council, 2023a)⁹¹. After this, there are several conditional extensions of the data exclusivity protection period available:

- 24 months: If conditions for market availability have been met;
- 6 months: If the product demonstrably addresses an unmet medical need⁹²;
- 6 months: If the product contains a new active substance and comparative trials have been conducted to support the initial authorisation application;
- 12 months: If the product is approved for an additional therapeutic indication with demonstration of significant clinical benefit in comparison with existing therapies.

For a product that fulfils all of the above conditions, a cumulative duration of data exclusivity of ten years can thus be reached. At the end of the data exclusivity period, a further two years of (unconditional) market protection apply⁹³. This means that the maximum duration of regulatory protection has increased from 11 years under the current system to 12 years, but with much stricter conditions for obtainment of that maximum duration. The expectation is that, for most products, the total period of regulatory protection will decrease compared to the present situation.

The first condition, potentially extending the data exclusivity by two years, requires the product to be “continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid.” For centrally authorised products, this automatically means that the product must be supplied in *all* Member States. Additional provisions clarify that the requirement is considered fulfilled also if a Member State has provided a waiver or if a positive decision has been obtained regarding inclusion in a positive list of products covered by the national health insurance system⁹⁴ (European Parliament & European Council, 2023a).

These proposed changes to the duration and conditions for data exclusivity are relevant in the context of the SPC proposals because they may act as somewhat of a counterweight to the abolishment of the sunset clause (see Section 5.2.1). Additionally, it potentially changes the relative importance of the

⁹¹ Art. 81(1): “The regulatory data protection period shall be six years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.”

⁹² Art. 83: “Medicinal products addressing an unmet medical need. (1) A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met: (a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality; (b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population. (2) Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as addressing an unmet medical need. (3) Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].”

⁹³ Art. 80(1): “The data referred to in Annex I, originally submitted with the view to obtaining a marketing authorisation shall not be referred to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81”. Art. 80(2): “A medicinal product concerned by a subsequent marketing authorisation referred to in paragraph 1 shall not be placed on the market for a period of two years after the expiry of the relevant regulatory data protection periods referred to in Article 81”.

⁹⁴ Art. 82(2): “To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation. [...] The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall: (a) confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or (b) waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation. Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a).”

different forms of market protection, including the SPC. A 2018 analysis of the incentive and reward system on medicinal products in the EU determined that regulatory protections are increasingly commercially important and that they are often the last effective form of protection on a product (Copenhagen Economics, 2018). If the average duration of data exclusivity is shortened, it becomes more likely that this role is fulfilled by the SPC protection. However, given that regulatory protection and SPC certificates are not mutually exclusive and that the two types of protection differ in their scope of protection, there is no reason for patent holders to choose between these rather than reap the benefits from both. Thus, whilst the relative economic value of the SPC may increase as a consequence of the proposed changes, they are unlikely to impact on the number of SPC applications or on the number of markets for which SPC protection is sought.

b. Modulating orphan market exclusivity

The proposed revision for the pharmaceutical legislation not only includes changes to the system of regulatory protections for all medicines but also to the current system whereby designated orphan medicines, upon authorisation, can obtain a 10-year period of market exclusivity. The changes similarly seek to link access to the incentive to the value of innovation and to improved access. The impact assessment again explored three separate options:

Table 6: Options considered for modulating orphan market exclusivity

	Option A	Option B	Option C
Orphan market exclusivity	Market exclusivity for orphan medicinal products maintained; + 1-year transferable regulatory protection voucher for products addressing HUMN	Market exclusivity abolished for all orphan medicinal products	Variable duration of market exclusivity, depending on product type: <ul style="list-style-type: none"> • 10 years for HUMN • 9 years for new active substances • 5 years for well-established use applications + 1 year based on patient accessibility in all relevant Member States for HUMN and new active substances
HUMN = High Unmet Medical Need			

Source: (European Parliament & European Council, 2023b)

The proposal for the revised pharmaceutical legislation is based on Option C, which maintains market exclusivity as an incentive for successfully developed orphan medicines but modulates the duration of that exclusivity based on product characteristics. The current duration of 10 years will no longer be the norm; instead, it will be reserved for a much smaller group of products for which it is deemed that they address a ‘high unmet medical need’. For most other products, the duration will be shortened to 9 years whilst for products that have been repurposed the duration is brought down even further, to just 5 years. The first two groups of products can benefit from one additional year of exclusivity if they are made accessible in all relevant Member States. Although the proposal thus creates an option for up to 11 years of exclusivity, it places rather strict conditions on this and it is likely that, for the large majority of products, the duration of exclusivity would be shortened by one year compared to the current situation.

Analogous to the proposed modulation of the duration of data exclusivity, the proposed changes can be expected to affect the relative importance of different forms of market protection. However, orphan

market exclusivity is reserved for a relatively small number of products and is not mutually exclusive with SPC protection. There is therefore no obvious reason why this change would directly impact a patent holder’s decision to apply for an SPC certificate.

c. Paediatric SPC extension

In the impact assessment for the development of the proposal for the revision, various options were considered with regards to the current 6-month SPC extension granted for completion of the PIP (Table 7).

Table 7: Options considered for modulating the paediatric SPC extension

	Option A	Option B	Option C
SPC extension	6 months SPC extension maintained For UMN: +12 months SPC extension OR 1-year transferable regulatory protection voucher	No more SPC extension; requirement for completion of PIP is maintained	6 months SPC extension maintained (no additional incentives)

Source: (European Parliament & European Council, 2023b)

The current proposal is based on Option C, meaning that the duration of protection will remain the same as before. However, the proposal would introduce some changes to the scope of products that fall within the requirement of submitting a PIP.

Under the current regulation, the requirement for submission of a PIP can be waived for products or classes of medicinal products if there is evidence, among other things, “that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations”⁹⁵ (European Parliament & European Council, 2006). In the evaluation of the Paediatric Regulation, it was found that this clause is too broad and allows waivers to be granted for products that, based on their mechanism of action, may be efficacious against a disease in children that is different from the one for which it was initially designed for use in adults (European Commission Health and Food Safety Directorate-General, 2020). This applies in particular to medicines that may be used in treatment of children with cancer. The proposal has therefore amended this clause by specifying that the waiver can be granted under such conditions unless “the product is directed at a molecular target that on the basis of existing scientific data, is responsible for a different disease or condition in the same therapeutic area in children than the one for which the specific medicinal product or class of medicinal products is intended for in the adult population” (Art. 75. 1(b)(European Parliament & European Council, 2023b).

By further limiting the scope for granting of waivers, the number of medicinal products for which submission of a PIP is required is likely set to modestly increase. Consequently, more products may become eligible for a paediatric SPC extension. In the impact assessment for the development of the proposed revision, the Commission estimates that the amendment to the waiver conditions will translate into three additional PIPs per year and one additional SPC extension reward (European Commission, 2023a). The proposal foresees in several other changes to the regulatory system for paediatric medicines that are intended to accelerate access. These, however, are not expected to intersect directly with the SPC proposals and are therefore here not further discussed.

⁹⁵ Art. 11(1b): “Production of the information referred to in point (a) of Article 7 (1) shall be waived for specific medicinal products or for classes of medicinal products, if there is evidence showing any of the following: [...] (b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations.”

5.2.3. Expanding the scope for the centralised procedure

The proposal for revision to the EU pharmaceutical legislation foresees expansions to both the mandatory and the optional scope for the centralised procedure for marketing authorisation (European Parliament & European Council, 2023b). These changes are said to be necessary to adapt “to the realities of the market and technological development as well as a need to ensure a centralised assessment for certain categories of medicinal products.”

Theoretically, the expansion of the mandatory scope could impact on the type and volume of products that meet the eligibility criteria for a unitary SPC certificate or for using the centralised SPC application procedure (or the combined application) since these routes require the product to be covered by a centralised marketing authorisation. However, as discussed in Section 2.3, most innovative products nowadays are already authorised in the EU through the centralised procedure. Bringing products for which the procedure was previously optional, yet common, into the mandatory scope may therefore not have major impact on current practice.

The proposal expands the criteria for optional access to the procedure to include also generic and biosimilar products. This expansion may have more substantial consequences for the number of products that are centrally authorised. However, since such products are typically not protected by a basic patent, they are unlikely to be eligible for SPC protection, regardless of the route of application or the territorial scope of the certificate.

Table 8: Product scope for the centralised procedure for marketing authorisation

Scope	Current	Proposed
Mandatory	<ul style="list-style-type: none"> • Products derived from biotechnology; • Advanced therapy medicinal products; • Orphan medicinal products; • Medicinal products for human use which contain an active substance authorised in the Union after 20 May 2004 and which are intended for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune disfunctions, and viral diseases. 	<ul style="list-style-type: none"> • High-technological medicinal products, particularly those resulting from biotechnological processes; • Priority antimicrobials; • Orphan medicinal products; • Paediatric use medicinal products; • Any medicinal product that includes an active substance not authorised before the last important change to the scope of the centralised procedure in 2004.
Optional	<p>Any medicinal product not appearing in the Annex [...], if:</p> <ul style="list-style-type: none"> • The medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community; or • The applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at Community level. 	<ul style="list-style-type: none"> • Medicinal products which, although not belonging to the categories of products to be authorised by the Union, are nevertheless therapeutically innovative; • Medicinal products which, although not innovative, may be of benefit to society or to patients, including paediatric patients, if they are authorised from the outset at Union level, such as certain medicinal products which can be supplied without a medical prescription.

Source: Current (European Parliament & European Council, 2004) and proposed (European Parliament & European Council, 2023b)

5.2.4. Introduction of a transferable data exclusivity voucher for antimicrobials

The Commission sees an urgent need to incentivise the development of new priority antimicrobials to combat antimicrobial resistance. To this end, it is proposing the introduction of a transferable data exclusivity voucher, which would grant its holder one year of additional data exclusivity (European Parliament & European Council, 2023b). The holder of the voucher may use this exclusivity on any product in its own portfolio or sell it on to another party for use on one of their products. This exclusivity means that the voucher potentially holds very significant economic value. The voucher is therefore bound to strict conditions and requirements, including obligations on supply and on transparency regarding development costs. A maximum of 10 vouchers will be available over a 15-year period.

As with the proposed modulations to the system of regulatory protections, making their duration contingent upon fulfilment of certain conditions (see Section 5.2.2), the transferable data exclusivity voucher introduces changes to the relative importance of different forms of market protection. For products where the regulatory protection would otherwise have ended 12 months or less before the SPC protection, use of the voucher would extend the overall duration of market protection by a

maximum of one year.⁹⁶ The 2018 analysis of pharmaceutical incentives suggests that for around 10 percent of products the SPC is the last protection to expire, but does not provide data on how often this falls within 12 months of the end of regulatory protection (Copenhagen Economics, 2018).

Although the (economic) impact of the transferable exclusivity voucher for priority antimicrobials may be very substantial at product level, its intersection with the current SPC proposals will be minimal. Even if the full number of available vouchers is issued, which may prove unlikely in view of the current dearth of development in this area, no more than ten products could benefit from the extension. Furthermore, because of the existence of concurrent forms of market protection, the extension of the effective term of protection overall may be less than 12 months. For the relative value of different forms of market protection in this system, it is largely irrelevant whether the SPC certificate has unitary effect or not⁹⁷.

⁹⁶ For instance, if the full period of regulatory protection (data exclusivity, including any conditional extensions + market protection) ends 4 months before the SPC protection (including any paediatric extension), the transferable data exclusivity voucher would allow the data exclusivity to be extended by 12 months. As a result, the last layer of protection (namely the market protection) will end 8 months (12-4) after the end of the SPC protection.

⁹⁷ The main potential difference arises from the date at which an SPC certificate was issued. For unitary SPC certificates, the duration of both regulatory protection and SPC protection will be exactly equal in all AUPC countries. For certificates without unitary effect, small variations in the date of issuance may continue to exist.

6. POTENTIAL IMPACTS OF THE SPC REGULATIONS

For this study, the potential impacts of the proposed SPC regulations have been explored in four main areas:

- Harmonisation of the SPC system and administrative simplification; from the perspective of SPC applicants as well as that of public authorities tasked with all procedural tasks, from filing of the application, to examination, granting and litigation;
- Cost implications to authorities and applicants;
- Access to medicines; considering both innovative and generic medicines;
- The costs on health care systems in EU Member States.

6.1. Harmonisation and administrative simplification

6.1.1. Divergence of granting decisions

One of the main objectives of the SPC proposals, and in particular of the introduction of the unitary SPC and the centralised assessment, is to reduce any divergence that exists currently between Member States in the implementation of the regulatory framework, including in granting decisions. Although the Commission has indicated that existing case law has already substantially reduced different interpretations of the SPC Regulation that have resulted in divergent outcomes of the examination of applications, the proposed system would largely eliminate this possibility all together.

For all future SPC applications, except for those that are entirely national and which are expected to become rare, the examination opinion(s) will be drafted by a single authority, i.e., the EUIPO. For the unitary SPC, a single examination opinion will be prepared and for the centralised non-unitary SPC, a series of examination opinions with one for each Member State. In the case of the unitary SPC this means that the decision to grant a certificate or reject an application automatically leads to the same outcome in all AUPC participating countries.

Under the centralised assessment for non-unitary SPCs, the formal granting of a certificate remains a national responsibility, but the examination opinion issued by the EUIPO is binding: Member States do not have the possibility to dismiss this opinion. It is nevertheless still possible that the conditions for granting are fulfilled in some but not all Member States so that the EUIPO will issue diverging opinions for different groups of countries, purely based on the varying national factual situations which may affect the outcome of the SPC examination. This remaining divergence, however, does not stem from different national interpretations of the regulatory framework but rather from inherent differences in the fulfilment of underlying criteria (e.g., because the application is based on a national rather than a European patent, or because in some jurisdictions there might be an earlier national marketing authorisation for the product) and cannot be avoided.

It is worth noting that the SPC proposals do not allow for an application for a unitary SPC to be converted into a centralised non-unitary application. Such conversion may be needed, for instance, if national divergence in aspects of the application means that the application for a unitary SPC does not meet all requirements in all AUPC Member States. Since for medicinal products a unitary SPC can only be granted (or rejected) for the whole of the territory, in this case the entire application must be rejected even in those countries where the criteria would be fulfilled. This differs from the proposal for plant protection products, which allows to limit the territorial scope of a unitary certificate to fewer

countries than the entire territory of the underlying unitary patent⁹⁸ (European Commission Directorate-General for Internal Market, 2023a). The justification for this is based on the fact that, for plant protection products, there are no centrally granted authorisations. Therefore, the proposed system builds in a form of flexibility to counter the situation where an authorisation would not have been granted in one or more AUPC Member States, whilst it would have been granted for others. As a result, the unitary SPC for a plant protection product might be territorially limited to those countries only where an authorisation has been granted, whilst the unitary SPC for such plant protection products would not be valid in those countries where a marketing authorisation has not been obtained.

6.1.2. Rigour of the assessment and quality of the SPC certificate

Differences in granting decisions between Member States may have been due, at least in part, to varying levels of expertise and capacity within national patent offices. In evaluation studies, as well as in the recital to the SPC proposals, it has been recognised that relatively few Member States have the expertise required to conduct a substantive examination of the application and some countries conduct only a minimal substantive examination. The introduction of a centralised assessment removes the influence of this factor as all Member States will draw upon the same expertise.

At present, the EUIPO itself does not yet possess this expertise or capacity. It will therefore need to invest in developing this capacity internally, as well as make effective use of the expertise already present in national patent offices, by including national examiners in the examination and appeal proceedings. Although the SPC proposals appear to recognise a need to select qualified and independent examiners⁹⁹, they also introduce additional selection criteria that could interfere with this focus on quality. Specifically, the proposals indicate that in regard to the panel the EUIPO shall ensure that:

- There is geographical balance amongst the participating offices;
- The respective workload of the examiners is taken into account;
- No more than one examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].

Particularly the requirement for geographical balance may prove challenging. In the unitary SPC proposal, the Commission explicitly recognises that, although qualified examiners can be found in national patent offices, “competencies and skills in SPC matters are scarce”. Given the relatively small pool of experts available, it may be difficult to achieve the desired geographical balance. If, on the other hand, experts are nominated on the basis of their geographical location rather than on their qualifications, this could risk lowering the standard of the examination.

The challenge is compounded by the fact that, according to the proposals, also members of the Boards of Appeal may be drawn from among national examiners. This potentially creates a significant bottleneck to setting up both an examination panel and a Boards of Appeal that are staffed with sufficiently qualified, yet distinct examiners. The possibility of adding national examiners to the Boards

⁹⁸ Art. 25: “(1) Where the unitary effect of the basic patent is revoked while the application for a unitary certificate is still pending, the holder of that application may, subject to a fee, request the conversion of that application into a centralised application for certificates. (2) Where the unitary effect of the basic patent is revoked after the unitary certificate has been granted, the holder of that certificate may, subject to a fee, request the conversion of that unitary certificate into national certificates.”

⁹⁹ See, for instance, under (26), p.18: “To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the procedure, in particular as regards qualification and conflicts of interest.”

of Appeal furthermore raises some questions about the independence of this body. Although the proposals indicate that these examiners “may not be the same examiners already involved in the examination of the centralised applications or applications for unitary certificates”¹⁰⁰, one might argue that proper independence requires that members of the examination panel and of the Boards of Appeal are not drawn from the same pool.

Two extreme scenarios best illustrate the potential advantages and risks of the new assessment procedure:

- If the expertise of the EUIPO is sufficiently developed and the selection of national examiners for the panel is done such that a high overall standard of expertise is achieved, the new system should provide an examination procedure that is as rigorous, or more, as that of the current ‘best practice’ in any Member State. For countries that currently have limited or no expertise in this area, the centralised assessment will therefore raise the ‘quality’ of SPC certificates granted, meaning that there will be less ground to appeal an examination opinion or contest a certificate once granted in court.

For SPC applicants, consequences may vary depending on the context. On the one hand, a higher quality of the examination can increase legal certainty: once a certificate has been granted, it is less likely that a court will rule to invalidate this due to incorrect interpretation of the Regulation or incorrect evaluation of the application¹⁰¹. If this, in turn, means that third parties are less likely to initiate actions for declaration of invalidity, developers may incur fewer costs from litigation and are better able to benefit from the SPC protection. On the other hand, applicants can also benefit from lower examination standards as this increases their likelihood of still obtaining an SPC certificate even when there may be cause for refusal. In such instances, more stringent examination could result in the denial of a certificate that currently could be granted in certain countries.

Higher examination standards may result in fewer SPCs being granted overall. For generic manufacturers, this creates space for bringing generic medicines to market earlier. Additionally, a higher quality of certificates issued would reduce the need for generic manufacturers to oppose the application or contest the certificate in court. This creates more certainty for generic manufacturers about when they will be able to enter a market and allow them to prepare accordingly.

- By contrast, for countries where applications for SPC certificates are already subjected to thorough examination, relinquishing this responsibility to the EUIPO’s examination panel can pose a risk. If the examination standard of the centralised assessment does not reach the high levels currently achieved in some Member States, those countries will face SPC protection being granted for products for which they, under a national assessment procedure, would have denied the application. Whilst the newly proposed system provides several avenues for third parties to oppose the award of a certificate or initiate action for a declaration of invalidity, these routes involve greater costs and efforts than if the initial examination had been done to the currently existing standard in the first place.

Mirroring the first scenario, lowered examination standards can both benefit and hurt developers. More SPCs may be granted initially, but in parallel the likelihood of contentious

¹⁰⁰ In accordance with Art. 166(5) of Regulation (EU) 2017/1001 (European Parliament & European Council, 2017).

¹⁰¹ A change to any of the underlying criteria that would affect the eligibility of the product and which occurs *after* the examination opinion and award of the certificate could, of course, still give grounds for legal action and invalidation.

certificates being litigated would increase. Generic manufacturers would be required to invest more into proceedings to attack the certificates.

Overall, the SPC proposals hold the potential to level existing differences in the standards of examination of SPC applications but whether that results in a sufficiently high standard will depend primarily on the composition of the examination panel and on the expertise developed in-house by the EUIPO. It is therefore important to ensure that any implementing acts provide well-considered guidance on the composition and functioning of the examination panel, to safeguard the quality of the examination opinions. At the level of the EUIPO, adequate investments will be needed to ensure that the new SPC division is equipped to fulfil its responsibilities. Not only does this entail training or recruiting staff with the required competencies but also developing the processes and systems needed to support them in their duties.

The proposals offer no details on the duration of the term that examiners would serve on the examination panel, nor on how many terms they could serve. For this, further an implementing act must still be prepared.

6.1.3. Likelihood of litigation

One of the aims of the SPC proposals is to bring greater legal certainty around the procedure for granting SPCs and, in doing so, reduce the need for litigation. There are several points to consider when predicting whether these proposals are likely to achieve this aim.

- One potential source of litigation derives from the (lack of) rigour with which the examination is conducted. Applicants, generic manufacturers, or third parties may feel that the examination authority has not fully or correctly considered all relevant information and that therefore the examination opinion is incorrect. If so, they have the opportunity to oppose the decision. Section 6.1.2 raised the possibility that the centralised assessment, both for the unitary and non-unitary SPC, will lead to a higher quality of the examination and thereby decrease the likelihood that there are grounds for litigation (including opposition). Furthermore, by allowing third parties to submit written observations during the assessment, there is a greater chance that all relevant information is considered even though these observations may be disregarded by the examination panel. This too could diminish the need for litigation. These expectations assume that litigation is initiated only when a party sees genuine grounds for doing so and is not done frivolously.
- At the same time, the proposals introduce various new procedures for opposition and appeal against an examination opinion (see Sections 4.3.4 (unitary SPC) and 4.4.4 (centralised non-unitary SPC)), including the possibility for third parties to initiate an opposition. Since the EUIPO is an EU agency, its decisions may be appealed at the Boards of Appeal and the European General Court, and, where applicable, may be referred to the CJEU. Those procedures have largely no equivalent under the current national system. Likewise, the application for a declaration for invalidity of a unitary SPC and its corresponding appeal options, do not exist under the current national system. Given the large economic interests in the pharmaceutical sector, it is likely that all parties affected by a decision will make full use of the options at their disposal to contest or defend an SPC certificate. This could well mean that the new SPC system will in fact increase, rather than decrease the use of legal proceedings. If so, this will inevitably lead to greater legal costs for all parties involved in these proceedings.
- A separate source of litigation currently stems from the fact that, thus far, decision-making on the granting of SPC certificates has been an exclusively national responsibility. Different national interpretations of the EU legal framework have triggered legal proceedings rising to

the level of the CJEU. Whilst the new system will largely remove the possibility for divergence of national interpretations, it will remain possible to have a case be referred to the CJEU when there are questions over the EUIPO's interpretation of the framework. However, as many of the provisions of the SPC regulation have already been the subject of at times multiple referrals to the CJEU, fewer provisions remain that may require interpretation. Whether the SPC proposals will give rise to new issues that require interpretation by the CJEU is, as yet, uncertain. However, as with any legislative change, it is probable that further legal clarification will be needed.

6.1.4. Administrative streamlining

Another of the proposals' aims is to reduce the cost and burden of obtaining or maintaining SPC protection. In the impact assessment, the Commission predicts that "a unitary SPC will also benefit European industry in reducing internal time and resources needed for the SPCs filings on each product." The degree to which the new system will allow for administrative streamlining varies across the different procedures.

a. Application for a certificate

Consistent with the proposals intentions, one may expect that filing an application for a unitary SPC will be administratively a simpler procedure than the current system of filing parallel applications in each of the national jurisdictions where SPC protection is sought. Fees for application and annual renewal will also be paid directly to the EUIPO rather than to separate national patent offices. However, given that at present not all Member States participate in the AUPC, it is likely that for many, or even most, products the unitary SCP will be used alongside the centralised assessment in a combined application. In these instances, it will remain necessary for applicants to participate in parallel procedures and to deal not only with the EUIPO but with national patent offices or courts as well. Thus, whilst the proposals will certainly support a degree of administrative streamlining of the application procedure, some duplication will inherently remain as long as not all Member States participate in the AUPC.

b. Procedures for opposition and appeal

The proposals introduce various procedures for opposition, appeal and invalidation, with some aspects of the options varying between the different routes of application.

- For a unitary SPC, the new procedures represent a simplification compared to the current situation by introducing a single point where such proceedings must be initiated, namely the EUIPO. Under the current system, separate proceedings must be initiated in each applicable jurisdiction with the corresponding national competent authority or court. Any decision resulting from these proceedings has standing only in that jurisdiction. By contrast, any decision regarding the granting, rejection or invalidation of a unitary SPC applies in all Member States that participate in the AUPC. This could therefore significantly reduce the number of procedures.
- For non-unitary SPCs that have been processed via the centralised assessment, the situation is more complicated. Despite the assessment being done centrally, the EUIPO issues separate examination opinions for each country included in the application. As a result, proceedings to oppose or appeal an examination opinion at the EUIPO are also specific to that country and multiple proceedings can occur in parallel. It is, as yet, unclear if, or how, the EUIPO might seek to 'bundle' proceedings relating to examination opinions for different countries into a single procedure. For such bundling to be legally permissible, the individual cases would need to relate to the same facts and legal issue(s).

- Although the Commission has stated that, under the combined application, there will be a single opposition and appeal procedure (see Section 4.5), in practice this may not always be possible. For example, a combined application may not meet the criteria for a unitary SPC certificate but does fulfil the criteria for a centralised non-unitary SPC certificate in at least one non-AUPC country. This could then simultaneously give rise to an appeal against the negative opinion for the unitary SPC application and a third-party opposition against the positive opinion for the centralised national SPC. How the EUIPO would bring these two proceedings into a single procedure has not been specified and may, in fact, not be possible. It is furthermore not clear how a decision in one proceeding could feed into decision-making in the other.

c. Procedure for declaration of invalidity

Some new complexity may arise from the introduction of the option for third parties to file for declaration of invalidation of a certificate before the EUIPO. It is somewhat unclear why the Commission has deemed this necessary. The new system already includes multiple opposition and appeals procedures relating to the examination opinion. Moreover, claims for invalidity can already be filed with the competent court (for unitary SPCs, the UPC; for centralised non-unitary SPCs, national competent courts, and the UPC if the basic patent underlying the SPC has not been opted out), as can counterclaims for invalidity in, for instance, patent or SPC infringement proceedings.¹⁰² The added value of this option, which may result in increased legal complexity and litigation, is therefore debateable. This is even more so as any decision under the procedure for declaration of invalidity can again be appealed at the European General Court, and where applicable to the CJEU. In the justification for its inclusion in the proposal, the Commission refers to the Charter of Fundamental rights. It is unclear, though, what rights the Commission believes would be violated by not including the possibility. Even without the procedure, the possibility to invalidate an SPC for the entire territory at the competent court (i.e., the UPC) would remain.

6.2. Cost implications

For any EU legislative proposal an impact assessment, including an estimation of the budgetary implications, is mandatory, considering both one-off and recurring costs. Since the options selected for the current SPC proposals are closely in line with those for which the impact assessment was conducted¹⁰³, any cost estimates presented in this study are that of the Commission (European Commission, 2023a). No independent evaluation of the accuracy or completeness of these estimates has been conducted as part of this study and, where quantitative cost data have been included, this has been done solely for the purpose of placing the study findings into more context.

6.2.1. Costs for the central examination authority (EUIPO)

The Commission states that, like the existing SPC regulatory framework, the proposals will “have no impact on the EU budget, since the system will remain fully self-funded by applicants’ fees”. It furthermore expects that the set-up costs for execution of the EUIPO’s new functions, including the costs for new digital systems, can be financed from the EUIPO’s accumulated budgetary surplus (European Commission, 2023c). The Commission estimates the set-up costs to be around EUR 1.5 million. This includes, for instance, the appointment of examiners; preparation of guidelines, work instructions and templates; training of personnel; creation of an IT system and setting up the Boards of

¹⁰² Art. 32(1)(d) AUPC: “[The Court shall have exclusive competence in respect of:] (d) actions for revocation of patents and for declaration of invalidity of supplementary protection certificates”.

¹⁰³ Specifically, the combined policy options 4 and 5 from the impact assessment.

Appeal. After this, recurring costs associated with administrative processing, examination, appeals and maintenance of systems are expected to total around EUR 1.8 million annually.

6.2.2. Application and maintenance fees

Whereas under the current system, applicants must pay an application fee to each national patent office with which an application is filed, for applications for a unitary SPC and for centralised (non-unitary) SPCs this must instead be paid directly to the EUIPO. The exact fees are still subject to negotiation and must be laid down in an implementing act. Nonetheless, the impact assessment provides some insight into the Commission's intentions (European Commission, 2023a).

For applicants seeking SPC protection in all 27 Member States by use of a combined application, it assumes a total filing fee of EUR 38,800¹⁰⁴. This is significantly higher than the total of EUR 8,800¹⁰⁵ in national application fees for the whole of the Union under the current system. The Commission expects that these additional costs will be offset by savings on maintenance fees and agent/attorney fees, resulting in a net saving of total costs of EUR 137,100 to applicants. It should be emphasised though that this amount represents a theoretical upper limit rather than the most common scenario. At present, applicants often do not seek protection in all 27 Member States and the fees proposed by the Commission are substantially higher than those currently charged by national authorities¹⁰⁶. For products for which an applicant seeks SPC protection in less than 10 Member States, the new system may no longer produce savings but rather raise costs¹⁰⁷.

The cost estimation for the impact assessment assumes that national patent offices may charge applicants an annual maintenance fee for certificates issued after a centralised or combined application procedure, but not an application fee for administrative processing of the certificate¹⁰⁸.

6.2.3. Translation costs

Importantly, as an EU Agency, the EUIPO must accept submissions in any of the official languages of the Union and, in turn, make its decisions available to the public in all these languages. This requires a significant amount of translation. To reduce the burden and costs of translation, the SPC proposals state that the EUIPO will be permitted to use verified machine translation, if appropriate. This permission applies to:

- Any documents and information submitted to the EUIPO, including applications for unitary SPCs and centralised applications and written third-party observations;
- Publication of examination opinions;
- Publication of information in the register for (applications for) unitary certificates and centralised applications.

¹⁰⁴ Assuming coverage of all 27 Member States. From Table 13, p.70 "PO4+5 costs and savings to applicants for receiving EU27 wide, five-year long SPC protection" of the impact assessment.

¹⁰⁵ Table 3, p.37 "PO0 (baseline) costs and savings to applicants for receiving EU27 wide SPC protection" of the impact assessment.

¹⁰⁶ On average, EUR 326 per country for the SPC application and between EUR 1,060 and EUR 1,667 for annual renewals. From Table 68, p.139 "SPC fee schedule per NPO in 2022 (EUR)" of the impact assessment.

¹⁰⁷ The impact assessment (p.138) states that, in comparison to the baseline, the combination of PO4+5 "always produces savings when ten or more Member States are covered. In case of the most common SPC duration of 3.5 years, the option is beneficial for covering five or more Member States."

¹⁰⁸ Table 65, p.135 "Total costs for an applicant of obtaining a five-year-long SPC protection in the whole EU (EUR)" of the impact assessment.

With respect to filing of centralised SPC applications, the SPC proposals indicate that the amount of text that would require translation is “extremely small” and would not pose a significant burden or cost to applicants. In fact, the Commission forecasts that, compared to the baseline situation, translation costs to applicants will decrease under the new system.

6.3. Access to medicines

6.3.1. Access to innovative medicines

Multiple factors influence whether patients in a given country can have access to a specific medicine. In the case of innovative medicines that are still under some form of market protection, access depends foremost on whether the marketing authorisation holder of the protected product has decided to place the medicine on that market, since generic versions are not yet allowed. As discussed in Section 2.3, such decisions are influenced by market characteristics, including market size and availability of treatment alternatives, as well as by economic factors. Access also depends on whether public authorities have admitted the product into the package of reimbursed care and on continuity of supply.

Whilst the existence of intellectual property rights and regulatory protections influences the conditions under which a product can be launched, the relationship between market protection and market launch decisions for innovative medicines is not clear-cut. A study published by the World Trade Organization, using data from 70 markets, found that, at least in high income markets, “the introduction of product patents has a positive effect on launch likelihood, especially for innovative pharmaceuticals” (Watal & Dai, n.d.). This argument, derived from patents, could in principle be extrapolated to SPC protection, although the effect is likely much smaller due to the more limited duration and scope of SPCs compared to patents. Furthermore, the basic principles of the SPC system apply equally in all EU Member States and therefore should not differentially influence market launch decisions.

Nonetheless, current national differences in the SPC system could in theory still affect the attractiveness of a specific market. For instance, markets where innovators have a better chance of obtaining SPC protection (or of effectively enforcing their SPCs) may be more commercially interesting, resulting in higher levels of market launch and faster access. At the same time, in markets that are intrinsically more commercially attractive and that, by consequence, see higher rates of market launch, innovators are more likely to seek SPC protection. The direction of any causal relation between SPC protection and market launch for innovative products is therefore difficult to establish empirically. It is probable that other factors play a larger role in influencing market launch decisions and the speed of access than any practical differences in the implementation of the SPC framework at national level.

In this light, it is questionable whether the introduction of the unitary SPC or of the centralised assessment will have any significant impact on access to innovative medicines. Although the proposals may help in further removing any divergence in the system and bringing Member States on more equal footing with each other in regard to how and when SPCs are granted, they will not affect any of the other underlying differences that contribute to unequal access. Rather, (some of) these factors are the focus of provisions in the proposed revision to the EU general pharmaceutical legislation. These revisions could, if successful, have substantially greater impact on promoting equitable access to innovative medicines than the SPC proposals.

6.3.2. Access to generic and biosimilar medicines

By nature, the SPC system is designed to create a temporary block against competition by generic and biosimilar medicines. The extent to which SPCs delay access is foremost determined by the following factors:

- Criteria for eligibility;
- The duration of protection conferred by the SPC;
- The rights conferred by the SPC;
- The number of markets in which a product is protected by an SPC.

All these factors are currently dictated by the existing SPC Regulation and are therefore, at least in principle, the same in all Member States (European Commission, 2009). The SPC proposals foresee no changes to either the duration of an SPC or to the rights it confers, irrespective of the route of application followed.

The proposals do, however, introduce some changes to the eligibility criteria that could affect how many and which products could be protected by an SPC. First, they contain new provisions for the nature of the basic patent invoked (a unitary patent for the unitary SPC; a traditional European patent for the centralised assessment) and a requirement that products have been centrally authorised by the EMA (except for purely national SPCs). These provisions, however, are unlikely to fundamentally change the nature or number of products in scope as, for any product that does not meet these requirements, the existing route of nationally assessed and granted SPCs will remain available.

A potentially more impactful change is the specification that it will no longer be possible to obtain a second SPC for the same product, even if based on a different patent (see Section 4.3.1). At present, CJEU case law allows this, and it is not uncommon for the same product to be protected by more than one patent.¹⁰⁹ The new proposals may thus limit the number of SPCs that can be granted. This change will apply to any SPC application, regardless of the route of application.

The biggest influence on access to generic and biosimilar medicines springing from these proposals may come from the territorial scope of protection for the unitary SPC. At present, SPC applications are often not filed in all EU Member States (see Section 3.1.3). The reason for not seeking SPC protection may be that the product has not been launched in a specific market and that therefore an SPC holds no commercial value there. Countries that see relatively few or late launches of innovative medicines include, for instance, Malta, Cyprus, the Baltic states and some Eastern European countries (Newton et al., 2022). This, in turn, correlates with the comparatively low numbers of SPCs applications filed in those countries (European Commission, 2023b). In markets without this SPC protection, generic competition is allowed from the moment the patent and any remaining regulatory protections have expired, even if the reference product remains under SPC protection elsewhere. However, the introduction of the unitary SPC would bring any country that has ratified the AUPC automatically within the territorial scope of protection, including those countries where at present SPC protection is often not sought. At least in theory, this could mean that generic entry remains prohibited even when the reference product is itself not on the market. Without safeguards, this could present a risk of further hindering access to medicines in countries where access is already problematic.

In this context, it is relevant to refer back to the changes the Commission is seeking to introduce in its proposal for revision to the EU general pharmaceutical legislation (see Section 5.2.2) to incentivise market launch in all Member States, including small markets. If adopted in finalised legislation, these provisions could act as a safeguard to protect access to (generic) medicines in more vulnerable markets. The current SPC proposals by themselves do not contain any provisions that would link SPC protection

¹⁰⁹ For instance, a product could have been protected as part of a larger class of compounds in one patent, could have been protected as such in another patent, could have been protected in the use for a different medical treatment in a third patent and so forth. It has been estimated that around 14.8% of products have been subject to the grant of more than one SPC (European Commission Directorate-General for Internal Market, 2018).

to market launch obligations or require applicants to waive their rights to SPC protection in markets where they will not launch.

It must also be recognised that the factors that prevent or delay launch of medicines in smaller and less wealthy markets apply not only to innovative medicines but also to generic and biosimilar ones. Even without SPC protection, these markets may not be sufficiently attractive by themselves to convince generic manufacturers to initiate manufacturing and sales operations as long as they cannot yet supply their product to larger and more profitable markets as well. The impact assessment prepared for the SPC proposals predicts that “a more centralised SPC system would not significantly slow down entry of follow-on products in smaller/lower income Member States, as these markets face delayed entries anyway, due to other factors than SPC” (European Commission, 2023a).

Beyond the here discussed factors that prescribe which products may benefit from SPC protection, for how long and where, it is important to consider the possibilities for generic manufacturers to oppose the grant of an SPC or contest it in court. These possibilities, if they result in refusal or invalidation of a certificate, can pave the way for earlier generic entry where this might otherwise have been unjustifiably prevented. The new SPC system introduces the opportunity for generic manufacturers to formally oppose a certificate prior to granting. One may assume that at least a share of all SPCs granted under the current system might have been rejected had there been an opportunity for third-party opposition. This assumption is somewhat supported by the observation that a (small) number of SPC certificates have been invalidated following court proceedings. It is, however, not possible to state in how many of these cases the certificates were invalidated due to issues that might hypothetically have been prevented by an opposition proceeding, should this option have existed. Without such data, the prediction that the new option for third-party opposition may result in fewer certificates being granted and could speed up generic access remains speculative.

One further consideration for the SPC proposals' impact on access to generic medicines lies in the possibility to file for invalidation of a certificate after it has been granted. At present, legal proceedings to invalidate must be filed nationally before the competent court in the jurisdiction where the certificate has been granted. Since a ruling in one Member State has no legal standing in another, it is possible for a certificate to have already been invalidated in one country but to remain under litigation in another, even if the basis for the proceedings is the same in both countries. Under the new unitary SPC system, this situation will no longer be possible since such proceedings will take place centrally before the EUIPO (in the case of an application for declaration of invalidity), or at the UPC (in case of a claim or counterclaim for invalidity of the SPC, or even the underlying patent). A decision on (declaration of) invalidity will take simultaneous effect in all AUPC countries, bar further appeals, thus enabling (or restricting, depending on the outcome) generic entry in all such countries at the same time. As such, this new system may bring increased equity of access to generic medicines among AUPC countries.

6.4. Transparency of information

Under the SPC proposals, all applications for SPC certificates (including those that have been granted as well as those refused well as any decisions for refusal) must be published in a register. For unitary certificates, there will be a single centralised register that is to be developed, kept and maintained by the EUIPO¹¹⁰ (European Commission, 2023c; European Commission Directorate-General for Internal

¹¹⁰ Recital (35): “To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted unitary certificates and their status. The register should be available in all official languages of the Union.” Further details regarding the contents of the Register are described in Art. 35 (European Commission, 2023c).

Market, 2023c). Likewise, any certificates under the centralised procedure must be included in a register, alongside those certificates being included in national registers in the jurisdictions where they have been formally granted (European Commission Directorate-General for Internal Market, 2023c). The proposals do not specify whether these are separate registers, but the information that must be contained in the registers is largely the same¹¹¹.

The creation of registers is done in the interest of transparency and the information may therefore be accessed by any third party free of charge. Alongside the register(s), the EUIPO will maintain an electronic database containing all documentation provided by applicants and third parties in respect to SPC applications, but access to the information in this database will be restricted.

The creation of a publicly accessible register containing information not only on the status of on SPC certificate but also on the underlying patent and marketing authorisation could add real value, including to generic manufacturers. Currently such information is difficult to access, and generic manufacturers cannot easily or freely obtain an overview of the status of SPC protection in all Member States. Rather, this information must be retrieved on a country-by-country basis and may not be easily accessible in the public domain. A centralised register will therefore greatly facilitate such overviews for generic manufacturers, but also may hold value for researchers and evaluators of health and intellectual property policy.

Although the introduction of a public register responds to a need expressed by different parties, including the generics industry, it carries some degree of risk as it may be used also by public authorities to inform decision-making on marketing authorisation of generic medicines. Such 'patent linkage', whereby approval is linked to the patent (or SPC) status of the reference product, is not allowed under the EU general pharmaceutical legislation (The European Commission, 2009). Despite this, the practice has continued to exist (Medicines for Europe, 2019). Thus, whilst any use of the register to inform marketing authorisation decisions for generic medicines would be in direct contravention of EU law, the register creates conditions that may facilitate this.

6.5. Impact on healthcare budgets in Member States

Against a backdrop of ageing populations, rising demand for health services and rising prices for innovative therapies, across the whole of the European Union countries are under pressure to ensure that health budgets are contained. Generic and biosimilar medicines play an important role in maintaining the affordability of health care systems, by introducing alternatives that are considerably cheaper than the reference medicine.

Any impacts from the SPC proposals on the health care budgets in Member States are therefore closely associated with their impacts on access to generic and biosimilar medicines. As discussed previously (see Sections 6.3.2 and 6.4), the SPC proposals may have both positive and negative consequences for such access, depending on country characteristics as well as product characteristics. On the one hand, they may facilitate generic entry by improving transparency of information and bring greater legal certainty for generic manufacturers as to when and where they may enter the market. On the other hand, the introduction of the unitary SPC could lead to an expansion of the geographic territory where products are protected by an SPC and thereby risk further delaying generic entry in some countries (see Section 6.3.2). The Commission has recognised this risk in its impact assessment for the proposals (European Commission, 2023a). Using a hypothetical scenario, it estimated the additional expenditure

¹¹¹ For centralised assessment applications, the register must additionally contain information on the designated Member States for which SPC protection is requested and on the particulars of certificates granted in each of the designated Member States.

countries would incur as a result of having to purchase the original medicine rather than a generic version as long as the reference product remains under SPC protection¹¹². The total estimated impact across all countries amounts to EUR 37 million per year. Whilst the impacts may be negligible in some countries, for others they could reach up to 0.5% of pharmaceutical spending in a year. The Commission, rather optimistically, argues that the additional costs may be re-invested into R&D for new therapies and thereby produce “a neutral cost-benefit outcome”. There is, however, no certainty that this will be the case, nor that any such investments translate into tangible benefits for patients or society.

With regards to access to innovative medicines, uncertainties about the impact on healthcare budgets likewise apply. Should the proposals achieve their intended aim of administrative simplification, this could act as an incentive for marketing authorisation holders to enter more markets or enter them more quickly. The reality remains, though, that launch decisions are typically informed by considerations other than the costs or administrative hassle of filing for SPC protection in a specific country. Should the SPC proposals somehow encourage greater access to innovative medicines, this may have some budgetary impacts as it potentially increases the number of medicinal products available the health care system can provide. However, in accordance with the TFEU⁸¹, Member States have full autonomy over the allocation of resources to health services and are therefore free to decide not to admit a particular medicine into the national package of reimbursed care. In general, increased access to innovative medicines is considered a desirable outcome, provided these medicines offer benefit to patients and are cost-effective, even if they contribute to increased costs.

¹¹² Considering only data for countries that have ratified the AUPC as these would be impacted by the unitary SPC.

7. POLICY RECOMMENDATIONS

Before offering specific policy recommendations, a few words of caution are in order. First, the proposals analysed in this study are a response to extensive evaluative studies and stakeholder consultations. This study has not re-examined the validity of the findings from these processes but rather has accepted them as the rationale behind the SPC proposals. This means, for instance, that the need for administrative streamlining and harmonisation has been taken as fact and that this study has analysed only whether the current proposals would be likely to achieve such a goal.

Second, this study has focussed purely on the proposed changes to the SPC system and, specifically, the introduction of the unitary SPC and centralised assessment. Questions such as whether the existence of an SPC system itself is consistent with policy objectives of the Commission or whether the duration of protection or the conditions for grant of an SPC are appropriate were outside the scope. Therefore, this study does not offer recommendations on such issues.

Third, the Terms of Reference for this study did not specify policy objectives against which recommendations should be provided. Although each of the SPC proposals articulates a set of objectives, these objectives are somewhat narrow and self-referential¹¹³. This means that they are not a suitable basis for policy recommendations. Instead, the Pharmaceutical Strategy for Europe has been taken as the guidance for the presented policy recommendations. This Strategy forms the basis for the ongoing work of the Commission and was supported by the European Parliament in a 2021 Resolution. The Pharmaceutical Strategy's objectives are:

- Ensuring access to affordable medicines for patients, and addressing unmet medical needs (e.g., in the areas of antimicrobial resistance, cancer, rare diseases);
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;
- Enhancing crisis preparedness and response mechanisms, and addressing security of supply;
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

Whereas the latter two objectives have only limited bearing on the SPC proposals, the first two provide a clear framework for recommendations. The main questions to consider therefore are whether, in their present form, the SPC proposals – and specifically the unitary SPC and centralised procedure – would help to 1) ensure access to affordable medicines for patients, and 2) support competitiveness, innovation and sustainability of the EU's pharmaceutical industry.

7.1. Ensuring access to affordable medicines

7.1.1. Access to innovative medicines

As set out in Section 6.3.1, it is not expected that the introduction of the unitary SPC or of the centralised assessment will have any major impacts on access to innovative medicines as the proposed changes to the SPC system will neither affect the eligibility for SPC protection nor the duration of the protection

¹¹³ The unitary SPC proposal states as its objective: "This proposal aims to simplify the EU's SPC system, as well as improve its transparency and efficiency, by creating a unitary certificate for medicinal products.". The SPC recast proposal states as its objectives: "As Regulation (EC) No 469/2009 has been amended several times, and since further amendments are to be made, that Regulation should, in the interest of clarity, be recast, which is the first objective of this proposal. [...] A second objective of this proposal is to introduce a centralised procedure for granting SPCs for medicinal products." The appropriateness of the unitary SPC and of a centralised procedure has therefore already been assumed in the proposals' objectives.

period. Furthermore, while the proposals may help in further removing any divergence in the system and may bring Member States on more equal footing with regard to how and when SPCs are granted, they will not affect any of the other underlying differences that contribute to unequal access to innovative medicines between Member States. Rather, such differences and ways to overcome these are the target of certain provisions in the proposed revision to the EU general pharmaceutical legislation, linking access to regulatory rewards and incentives to market launch requirements. These revisions could, if successful, have substantially greater impact on promoting equitable access to innovative medicines than the SPC proposals.

From the perspective of ensuring access to innovative medicines it is therefore important to ensure that provisions to increase market access in the proposal for the EU general pharmaceutical legislation are retained. Ideally, the two legislative processes for adoption of the EU general pharmaceutical legislation and of the SPC Regulations should be considered together, to ensure their alignment.

Recommendations

- In negotiations on the proposals for revision of the EU general pharmaceutical legislation, monitor the status of provisions aimed at increasing access to medicines in all Member States. If such provisions are weakened, alternative provisions could be considered linking eligibility for grant of an SPC to marketing obligations.

7.1.2. Access to generic and biosimilar medicines

Whereas the impact of the SPC proposals on access to innovative medicines is expected to be minimal, Section 6.3.2 outlined several ways in which they may affect the availability and affordability of generic and biosimilar medicines. These were:

- Increased opportunities for generic manufacturers and third parties to contest an SPC (either during assessment or after granting) could reduce the number of SPCs granted and therefore facilitate earlier entry of lower-cost generic medicines;
- Decisions to declare a unitary SPC invalid will apply in all participating Member States simultaneously, removing the possibility for a unitary SPC to remain under litigation in one country whilst already invalidated in another. This could allow earlier generic entry;
- More transparency about where and until when medicinal products remain under SPC protection allows generic manufacturers to better prepare for market launch. This may speed up generic entry.
- The wide territorial scope of the unitary SPC could mean SPCs are automatically granted in markets where otherwise there would have been no SPC protection. This may delay generic entry in those countries even if the originator product itself has not been placed on the market.

Whilst the first three effects are positive from the perspective of availability and affordability, the third one poses a risk to the timely entry of generic alternatives. The SPC proposals do not (yet) contain any provisions to mitigate this, although the proposed revisions to the EU general pharmaceutical legislation may offer some counterbalance by linking access to incentives to market launch. The SPC proposals could strengthen this by similarly linking SPC protection to a marketing obligation or otherwise requiring SPC applicants to waive their rights to SPC protection in markets where they have not launched. If, however, in practice the impact of the unitary SPC has no substantial impact on the availability of generic medicines in these countries, a separate provision of this kind may add unnecessary administrative complexity.

Recommendations

- Monitor whether parties that obtain a unitary SPC certificate use this right to block generic access in participating countries where the reference product has not been offered for or placed on the market.
- Based on results from the above, assess the necessity of adding a clause that unitary SPC protection applies only in markets where the holder of the unitary SPC has offered the product to the market within a specified time of the SPC protection taking effect.

7.2. Support competitiveness, innovation and sustainability of industry

Since the proposals do not introduce substantive changes to the conditions for obtaining SPC protection or to the duration of the SPC protection, any impacts on competitiveness of the innovative pharmaceutical industry would primarily derive from reducing the administrative burden on innovators associated with applying for and maintaining SPC certificates. For manufacturers of generic and biosimilar medicines, the central examination and opposition procedures for the unitary SPC will likewise reduce the administrative burden as they will be able to oppose the grant of a unitary SPC in a single procedure rather than having to do so in each jurisdiction separately.

At first glance, it would therefore appear that the proposals will offer administrative simplification for both innovative companies and for generics manufacturers. This could have a positive effect on the competitiveness of the pharmaceutical industry in the EU overall. However, to what extent the proposals will truly result in fewer and simpler procedures remains to be seen. As discussed in Sections 6.1.3 and 6.1.4, the introduction of additional procedures for opposition and multiple appeal procedures may ultimately result in lengthier procedures, more litigation and more uncertainty. If this indeed happens, this may also carry increased costs to users and third parties. It is therefore advisable to critically reassess the added value of each of these new procedures and determine whether further rationalisation of the system may be justified.

Of further note is that the current proposals do not provide for a conversion of a unitary SPC application into a centralised SPC. According to the unitary SPC proposal, the conditions for grant of an SPC must be fulfilled in all Member States simultaneously. It is, however, possible that there will be cases where the conditions for grant will be fulfilled in some but not all Member States simultaneously. The proposals do not provide for an alternative route in such an event, leaving the SPC applicant without any possibility to obtain an SPC. The national route is not available in this scenario, as the marketing authorisation for the medicinal product would have been granted by the EMA, which precludes applicability of the national route. The centralised route is also foreclosed, as it can only be used in cases where there is no unitary patent.

Recommendations

- Review the necessity for the multitude of opposition and appeal procedures available and, where justified, reduce these. In particular, the added value of the central application for declaration of invalidity at the EUIPO (Sections 4.3.6 and 4.4.6) should be carefully considered, given that there is already a possibility to invalidate the unitary SPC before the Unified Patent Court.
- Allow applicants to convert an SPC application into a centralised SPC application for those countries where the conditions for a unitary SPC are not fulfilled.

7.3. Additional considerations

7.3.1. Transfer of responsibilities from NPOs to the EUIPO

Although, for the largest part, the SPC proposals appear to be a balanced reflection of the outcomes of the various evaluation studies and consultations, a notable exception is the choice for the EUIPO as the examination authority for both unitary SPC applications and centralised applications (Section 4.7). Here, the proposals diverge significantly from the consensus among (innovative) industry stakeholders who would have preferred to see NPOs, either through a virtual office or through a mutual recognition procedure, or the EPO in this role. Whilst the choice for the EUIPO can be understood from the perspective of the Commission's desire to entrust these responsibilities to a body that, as part of the EU legal order, is accountable to the Member States, it also means that an entirely new infrastructure needs to be developed since the EUIPO currently has no competencies in SPCs.

It should therefore be expected that, for the EUIPO to be able to fully perform its responsibilities in line with the proposals, a certain amount of time is needed to develop the capacity, procedures and structures needed in-house for this. This will in turn require capital to recruit and train staff and to build the IT-infrastructure to support the processing of applications and set up a public register of all applications and grants. The impact assessment for the proposals estimates a one-off cost of around EUR 1.4 million for this, and further annual operating costs. Considering current rising inflation rates and increasing labour costs, this estimate may prove overly optimistic. The proposals understandably also do not detail how long the Commission anticipates the EUIPO will need to be able to ready itself for the new responsibilities.

The proposals furthermore note that the transfer of responsibilities to the EUIPO away from the NPOs will result in some loss of revenue to NPO from application and maintenance fees. Estimates for the loss of revenue range from EUR 20,000 (for a system based entirely on centralised filing and examination of SPC applications resulting in a binding opinion, PO4) to EUR 512,900 (for a system wherein a unitary SPC complements the unitary patent, PO5) per office annually. According to the proposals, this loss of revenue will be partially compensated by a transfer of a part of the renewal fees for unitary SPCs to NPOs where the SPCs have effect. However, the Impact Assessment states¹¹⁴ that there will be no maintenance fees for the unitary SPC, and that the maintenance fees for the SPCs granted under the centralised procedure will remain at the national level so it is unclear how this promise of compensation should be interpreted. NPOs for which examiners take part in the substantive examination for unitary SPC applications will also be remunerated for this. The level of compensation has not been specified in the proposals, but the transfer of responsibilities from NPOs to the EUIPO will almost certainly result in a net loss of income for NPOs. Additionally, it could have consequences for staffing in the NPOs, where fewer examiners may be needed. Whilst, at the system level, the benefits of the new SPC regime may outweigh these costs, the direct consequences to NPOs are worth consideration.

Recommendations

- Request the Commission to update and further explain its estimates for the set-up costs for the EUIPO. Additionally, the Commission together with the EUIPO could outline an action plan for development of the needed capacity at the EUIPO to ensure the continuity and quality of the system, including also a risk management plan.
- Request clarity from the Commission on the levels of compensation to NPOs resulting from the transfer of responsibilities to the EUIPO.

¹¹⁴ Table 65, page 135

7.3.2. Standards of examination

The goal of the new SPC system should be to attain the highest possible standards of examination. This goal is challenged by commitments in the proposal to ensure that there is a geographical balance among participating offices and a distribution of examiners across the EU territory. The current proposals provide no indication as to how the highest quality can be ensured with the other parameters in place.

Recommendations

- Request further clarification from the European Commission on how it intends to balance assurance of the highest quality standards in the examination with geographic balance.

7.3.3. Independence of Boards of Appeal

The SPC proposals suggest that national examiners can also be members of the Boards of Appeal. Despite the fact that the proposals indicate that national examiners hereto selected cannot also have taken part in the examination of the SPC application at issue, questions as to their full independence remain. In line with the current EU trademark regime, where examiners cannot be appointed as members of Boards of Appeal (as per Art. 166(9) of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trademark), it might be advisable to mimic this principle for the SPC system.

7.3.4. Cost impacts for applicants

In the impact assessment for preparation of the proposals, the Commission has estimated the cost impacts on all affected parties, including applicants. Based on these estimates, the Commission has concluded that the proposed system will result in net cost savings for any applicant seeking SPC protection in ten or more Member States or, in the case of an average duration of 3.5 years SPC protection, even when five or more Member States are covered. Some of the assumptions underpinning these calculations, however, could be called into question. In particular, attorney costs have likely been underestimated. The requirement that, for obtainment of a unitary SPC, the eligibility conditions must be fulfilled in all participating countries entails substantial additional work compared to a single national application. Likewise, a centralised SPC application produces draft opinions for each Member State. As these may vary, they will need to be individually examined (unless expressly indicated the opinions are identical) to allow for preparation of a response. A further point is the addition of new appeal and opposition procedures. If used, these procedures will also require the use of attorney services. As such, the overall attorney costs may well be considerably higher than those indicated in the Commission's impact assessment. If so, this will affect the point at which the new system will bring cost savings to applicants compared to the current situation.

The question of the validity of the Commission's cost estimates to applicants is particularly pertinent to SMEs. The Commission has conducted an 'SME test' as part of the impact assessment. From this it concludes that the proposals would bring 'originator SMEs' benefits by reducing administrative and attorney fees related to the filing and examination and limit related translation costs. However, compared to large pharmaceutical companies, SMEs may be less inclined to seek SPC protection in a large number of markets and may be more likely to fall below the 'tipping point' above which such savings are realised. If indeed the Commission's estimates have underestimated certain costs, particularly attorney fees, there exists a risk that SMEs could be adversely affected.

Recommendations

- Request further clarification from the European Commission on how it has prepared its cost estimates for applicants, including underlying assumptions about the frequency of use of procedures. If estimates must be revised upwards, carefully consider the impact of this on SMEs.

REFERENCES

- Barton, C. (2022). What Impact Will the New Unitary Patent System Have in Europe. *Pharmaceutical Technology*, *Pharmaceutical Technology*, 46(9).
- Copenhagen Economics. (2018). Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe.
- Council of the European Union. (2016, June 17). Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States. <https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>.
- de Jongh, T., Becker, D., Boulestreau, M., Davé, A., Dijkstal, F., King, R., Petrosova, L., Varnai, P., Vis, C., Spit, W., Moulac, M., & Pelsy, F. (2021). Future-proofing pharmaceutical legislation : study on medicine shortages: final report (revised). Publications Office of the European Union. <https://doi.org/10.2875/211485>.
- de Jongh, T., Radauer, A., Bostyn, S., & Poort, J. (2018). Effects of Supplementary Protection Mechanisms for Pharmaceutical Products.
- De Jongh, T., Velten, L., & Schrijver, L. (2021). Access to medicinal products. Policy Department for Economic, Scientific and Quality of Life Policies Directorate-General for Internal Policies. [https://www.europarl.europa.eu/RegData/etudes/STUD/2021/662910/IPOL_STU\(2021\)662910_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2021/662910/IPOL_STU(2021)662910_EN.pdf).
- DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20–33. <https://doi.org/10.1016/J.JHEALECO.2016.01.012>.
- Directorate-General for Internal Market, I. E. and Sme. (2023). Proposal for a regulation on compulsory licensing for crisis management. https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en.
- EP & C Patent Authorities. (2023). Unitary Patent and UPC. Epc.Nl. <https://www.epc.nl/en/faq/unitary-patent#:~:text=A%20European%20patent%20is%20registered,all%20participating%20member%20states%20simultaneously>.
- EUR-Lex. (2008, May 9). EUR-Lex - 12008E168. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12008E168>.
- European Commission. (2009). REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 concerning the supplementary protection certificate for medicinal products. In *Official Journal of the European Commission* (REGULATION (EC) No 469/2009). Official Journal of the European Commission.
- European Commission. (2020a). COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products SWD(2020) 292 final.

- European Commission. (2020b). *Pharmaceutical Strategy for Europe*.
- European Commission. (2020c). *Pharmaceutical Strategy for Europe*. In COM(2020) 761 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761>.
- European Commission. (2022). *Call for Evidence for an Impact Assessment: Medicinal & plant protection products - single procedure for the granting of SPCs*.
- European Commission. (2023a). *Commission Staff Working Document. Impact Assessment accompanying the documents: Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European*. In SWD(2023) 192 final.
- European Commission. (2023b). *Commission Staff Working Document Impact Assessment Report accompanying the proposal for regulations COM(2023)221, COM(2023)222, COM(2023)223 and COM(2023)231 SWD(2023) 118 final*.
- European Commission. (2023c). *Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013*.
- European Commission Directorate-General for Internal Market, I. E. and Sme. (2018). *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe: final report*.
- European Commission Directorate-General for Internal Market, I. E. and Sme. (2023a). *COM(2023)221 - Proposal for a regulation on the unitary supplementary protection certificate for plant protection products*. European Commission. https://single-market-economy.ec.europa.eu/publications/com2023221-proposal-regulation-unitary-supplementary-protection-certificate-plant-protection_en.
- European Commission Directorate-General for Internal Market, I. E. and Sme. (2023b). *COM(2023)223 - Proposal for a regulation on the supplementary protection certificate for plant protection products (recast)*. European Commission. https://single-market-economy.ec.europa.eu/publications/com2023223-proposal-regulation-supplementary-protection-certificate-plant-protection-products-recast_en.
- European Commission Directorate-General for Internal Market, I. E. and Sme. (2023c). *COM(2023)231 - Proposal for a regulation on the supplementary protection certificate for medicinal products (recast)*. https://single-market-economy.ec.europa.eu/publications/com2023231-proposal-regulation-supplementary-protection-certificate-medicinal-products-recast_en.
- European Commission Health and Food Safety Directorate-General. (2019). *Health systems and products Medicinal products VOLUME 2A Procedures for marketing authorisation*.
- European Commission Health and Food Safety Directorate-General. (2020). *Commission Staff Working Document Evaluation: Joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products*. In SWD(2020) 163 final. European Commission.

https://health.ec.europa.eu/system/files/2020-08/orphan-regulation_eval_swd_2020-163_part-1_0.pdf.

- European Parliament, & European Council. (1999). Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32000R0141>.
- European Parliament, & European Council. (2004). Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance). <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0726>.
- European Parliament, & European Council. (2006). Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. Official Journal of the European Union. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1901>.
- European Parliament, & European Council. (2012). REGULATION (EU) No 1257/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection. In Official Journal of the European Union (REGULATION (EU) No 1257/2012). Official Journal of the European Union.
- European Parliament, & European Council. (2017). Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R1001>.
- European Parliament, & European Council. (2023a). Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC COM/2023/192 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>.
- European Parliament, & European Council. (2023b). Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193>.
- European Patent Office. (2022). Member states of the European Patent Organisation. Epo.Org. <https://www.unified-patent-court.org/en/organisation/upc-member-states>.
- European Patent Office. (2023). Statistics & Trends Centre | Epo.org. <https://new.epo.org/en/statistics-centre#/technologyfields>.
- Hu, Y., Eynikel, D., Boulet, P., & Krikorian, G. (2020). Supplementary protection certificates and their impact on access to medicines in Europe: case studies of sofosbuvir, trastuzumab and imatinib. *Journal of Pharmaceutical Policy and Practice*, 13(1), 1. [Supplementary protection certificates](#).
- Kalindjian, A., Ralph, L., Middleton, S., Parkinson, S., Phillips, W., Romanelli, R. J., Alom, S., Rodriguez-Rincon, D., Marjanovic, S., Watkinson, C., Slag, M., & van der Erf, S. (2022). The financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue. <http://www.sirm.nl/>.

- Max Planck Institute for Innovation and Competition. (2022). Study on the options for a unified supplementary protection certificates (SPCs) system in Europe.
- Medicines for Europe. (2019). The anti-competitive effects of patent linkage. www.medicinesforeurope.com.
- Mejer, M. (2017). 25 years of SPC protection for medicinal products in Europe: Insights and challenges.
- Mondrup Pedersen, J., & Justesen, J. H. F. (2021). Denmark. In O. Ridderbusch & A. von Uexküll (Eds.), *European SPCs Unravalled: A Practitioner's Guide to Supplementary Protection Certificates in Europe* (Second ed.). Wolters Kluwer Legal & Regulatory. <https://law-store.wolterskluwer.com/s/product/european-spcs-unravalled-2e/01t4R00000OVWmmQAH>.
- Moore, T. J., Heyward, J., Anderson, G., & Alexander, G. C. (2020). Variation in the estimated costs of pivotal clinical benefit trials supporting the US approval of new therapeutic agents, 2015–2017: a cross-sectional study. *BMJ Open*, 10(6), e038863. <https://doi.org/10.1136/BMJOPEN-2020-038863>.
- Newton, M., Stoddart, K., Travaglio, M., & Troein, P. (2022). EFPIA Patients W.A.I.T. Indicator 2022 survey. https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf.
- Papadopoulou, F. (2018, January 28). Fine-tuning the SPC Regulation; a never-ending story? IpKitten.Blogspot.Com. <https://ipkitten.blogspot.com/2018/01/fine-tuning-spc-regulation-never-ending.html>.
- Papadopoulou, F. (2022, October 24). A new study on the options for a unified supplementary protection certificates (SPCs) system in Europe! Ip-Kitten.Blogspot.Com. <https://ipkitten.blogspot.com/2022/10/a-new-study-on-options-for-unified.html>.
- Piachaud-Moustakis, B. (2023a). Harmonizing Rules Governing SPCs for Medicinal Products. *Pharmaceutical Technology*, 47(2).
- Piachaud-Moustakis, B. (2023b). Harmonizing Rules Governing SPCs for Medicinal Products. *Pharmaceutical Technology*, 47(2).
- The European Commission. (2009). *Pharmaceutical Sector Inquiry Final Report*.
- Unified Patent Court. (2023). UPC Member States. <https://www.unified-patent-court.org/https://www.epo.org/about-us/foundation/member-states.html>.
- Watal, J., & Dai, R. (n.d.). PRODUCT PATENTS AND ACCESS TO INNOVATIVE MEDICINES IN A POST-TRIPS ERA. Retrieved June 16, 2023, from <https://www.iqvia.com/de-de/about-us>.

In April 2023, the European Commission adopted regulatory proposals introducing a Unitary Supplementary Protection Certificate (SPC) and a centralised assessment procedure for SPCs for medicinal products. This study analyses the potential impacts of these proposals on access to medicines, the administrative burden to applicants and the cost to national health systems. This document was prepared by Policy Department for Citizens' Rights and Constitutional Affairs at the request of the JURI Committee.

PE 753.104

IP/C/JURI/FWC/2019-001

Print ISBN 978-92-848-1124-3 | doi:10.2861/382152 | QA-04-23-915-EN-C

PDF ISBN 978-92-848-1123-6 | doi:10.2861/836176 | QA-04-23-915-EN-N